

# National Materials Program

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## Appendices



**Final Report of the Working Group**  
**SECY 99-250**

**Volume II**  
**May 2001**

# National Materials Program Working Group Report

examines

- *impacts of increasing number of Agreement States*
- *six options for a National Materials Program structure*

and

- *the following six issues as specified in SECY-99-250*

**Development of an overall program mission statement with defined top level goals and objectives.**

**Delineation of the respective roles and legal responsibilities of NRC and the Agreement States, including the Organization of Agreement States and the Conference of Radiation Control Program Directors, Inc.**

**Delineation of the scope of activities to be covered by the program and the need for statutory changes at both state and federal levels.**

**Establishment of formal program coordination mechanisms.**

**Establishment of performance indicators and a program assessment process to both measure program performance and to ensure program evolution.**

# National Materials Program

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## **SECTION VII**

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### **Appendices**

**Section VII contains the reference materials and detailed appendices supporting the explanations in the text of the report.**

**APPENDIX A****Acronyms Appearing in the Appendices**

<b>AEA</b>	<b>Atomic Energy Act</b>	<b>NARM</b>	<b>Naturally Occurring and Accelerator Produced Radioactive Material</b>
<b>AEC</b>	<b>Atomic Energy Commission</b>		
<b>AMA</b>	<b>American Medical Association</b>	<b>NAS</b>	<b>National Academy of Sciences</b>
<b>ANSI</b>	<b>American National Standards Institute</b>	<b>NCRP</b>	<b>National Council on Radiation Protection</b>
<b>AS</b>	<b>Agreement States</b>	<b>NEI</b>	<b>Nuclear Energy Institute</b>
<b>ASME</b>	<b>American Society of Mechanical Engineering</b>	<b>NERHC</b>	<b>New England Radiological Health Committee</b>
<b>ANSI</b>	<b>American National Standards Institute</b>	<b>NESHAPS</b>	<b>National Emission Standards for Hazardous Air Pollutants</b>
<b>ASNT</b>	<b>American Society of Nondestructive Testing</b>	<b>NIST</b>	<b>National Institute of Standards and Testing</b>
<b>CDC</b>	<b>Centers for Disease Control</b>	<b>NMA</b>	<b>National Mining Association</b>
<b>CRCPD</b>	<b>Conference of Radiation Control Program Directors, Inc.</b>	<b>NMED</b>	<b>Nuclear Materials Events Database</b>
<b>DOE</b>	<b>U.S. Department of Energy</b>	<b>NMP</b>	<b>National Materials Program</b>
<b>DOI</b>	<b>U.S. Department of Interior</b>	<b>NMPWG</b>	<b>National Materials Program Working Group</b>
<b>DOL</b>	<b>U.S. Department of Labor</b>	<b>NMSS</b>	<b>NRC Office of Nuclear Materials Safety and Safeguards</b>
<b>DOT</b>	<b>U.S. Department of Transportation</b>	<b>NORM</b>	<b>Naturally Occurring Radioactive Material</b>
<b>EDO</b>	<b>NRC Executive Director of Operations</b>	<b>NOV</b>	<b>Notice of Violation</b>
<b>EPA</b>	<b>U.S. Environmental Protection Agency</b>	<b>NRC</b>	<b>U.S. Nuclear Regulatory Commission</b>
<b>FDA</b>	<b>U.S. Food and Drug Administration</b>	<b>OAS</b>	<b>Organization of Agreement States</b>
<b>FTE</b>	<b>Full-Time Equivalent</b>	<b>OGC</b>	<b>NRC Office of General Counsel</b>
<b>HPS</b>	<b>Health Physics Society</b>	<b>OMB</b>	<b>Office of Management and Budget</b>
<b>HQ</b>	<b>NRC Headquarters</b>	<b>OSHA</b>	<b>U.S. Occupational Safety and Health Administration</b>
<b>IAEA</b>	<b>International Atomic Energy Agency</b>	<b>OSTP</b>	<b>NRC Office of State and Tribal Programs</b>
<b>IMC</b>	<b>Inspection Manual Chapter</b>	<b>PET</b>	<b>Positron Emission Tomography</b>
<b>IMNS</b>	<b>NRC Division of Industrial and Medical Nuclear Safety</b>	<b>RSO</b>	<b>Radiation Safety Officer</b>
<b>IMPEP</b>	<b>Integrated Materials Performance Evaluation Program</b>	<b>SDO</b>	<b>Standards Developing Organization</b>
<b>ICRP</b>	<b>International Commission on Radiological Protection</b>	<b>SNM</b>	<b>Society of Nuclear Medicine</b>
<b>MARSSIM</b>	<b>Multi-Agency Radiation Survey and Site Investigation Manual</b>	<b>SSRCR</b>	<b>Suggested State Regulations for Control of Radiation</b>
<b>MQSA</b>	<b>Mammography Quality Standards Act</b>	<b>TENORM</b>	<b>Technologically Enhanced Naturally Occurring Radioactive Material</b>
<b>MSHA</b>	<b>U.S. Mine Safety and Health Administration</b>		

## **Appendices**

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- A. Directives and References**  
This subsection provides documents that are background materials.
- B. Working Group Interactions and Communications**  
This subsection describes in depth the stakeholder outreach activities of the Working Group. Comments and responses are summarized.
- C. Evaluation of Program Elements**  
This subsection gives in depth information about program elements and suggested alternatives.
- D. Relative Decision Matrix**  
This subsection explains the relative decision matrix technique.



## **A. Directives and References**

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- **National Materials Program Working Group Charter**
- **SECY-99-250**
- **Section 274 of the Atomic Energy Act**

## APPENDIX A

# National Materials Program Working Group Charter

NRC formed a working group to provide the Commission with options for maintaining an infrastructure of supporting rules, guidance and other program elements needed for the nationwide materials program considering the anticipated increase in the number of Agreement States. The working group is composed of representatives of state governments and NRC. The Working Group will produce a report for the Commission's consideration.

### The Working Group Mission

The mission is to develop options for the Commission's consideration for creating a National Materials Program that will implement the following philosophy:

*To create a true partnership of NRC and states that will ensure protection of public health, safety, and the environment while:*

- *optimizing resources of federal, state, professional and industrial organizations;*
- *accounting for individual agency needs and abilities;*
- *promoting consensus on regulatory priorities;*
- *promoting consistent exchange of information; and*
- *harmonizing regulatory approaches while recognizing state and federal needs for flexibility.*

To accomplish the mission, the working group will consider the following issues:

1. the continuing trend for states to assume authority for the regulation of radioactive materials;
2. the potential impact of this trend on maintaining the infrastructure of the existing state and federal regulatory programs in the current fiscal environment and the increased fee burden on a decreasing number of NRC licensees to support generic activities;
3. the roles and legal responsibilities of NRC, Agreement States, Organization of Agreement States, Conference of Radiation Control Program Directors, Inc., and other organizations;
4. the need for statutory changes in federal and state programs for a National Materials Program;
5. the required elements and scope of activities in a materials regulatory program such as licensing, inspection, enforcement, training, event reporting, emergency response and program support activities including developing licensing and inspection guidance, developing program policy and guidance, developing standard review plans, providing laboratory support, and rulemaking activities;
6. the assessment process and performance indicators that could be used to measure the performance of a National Materials Program considering the current Integrated Materials Performance Evaluation Program process;
7. mechanisms for program coordination and program evolution;
8. the resource needs required for a National Materials Program and options for meeting those resource needs at both state and federal levels; and
9. accommodation of federal and state strategic performance goals and outcomes under a National Materials Program.

**APPENDIX A****National Materials Program SECY-99-250**

SECY-99-250

October 14, 1999

**FOR:** The Commissioners  
**FROM:** William D. Travers /s/ Executive Director for Operations  
**SUBJECT:** NATIONAL MATERIALS PROGRAM:REQUEST APPROVAL OF THE FORMATION OF A WORKING GROUP ON THE INCREASE IN THE NUMBER OF AGREEMENT STATES AND IMPACT ON NRC'S MATERIALS PROGRAM

**PURPOSE:**

To inform the Commission of the staff's plan to form a working group to address the impacts of the increased number of Agreement States and to provide advice to the Nuclear Regulatory Commission (NRC) on the National Materials Program.

**BACKGROUND:**

Presently, NRC exercises regulatory responsibility over about 5,310 material licensees. The 31 Agreement States regulate about 16,550 material licensees. Staff expects four additional States will become Agreement States by Fiscal Year (FY) 2003 and estimates that the number of NRC licensees will drop to approximately 4,000. At that time, the Agreement States will be regulating about 17,860 licenses. This shift in responsibility has significant implications for both NRC's materials program and the Agreement States. The process that NRC will use in the future to develop and maintain the infrastructure of regulations and supporting guidance applied by NRC and the Agreement States in their respective licensing and inspection programs should reflect this shift.

**DISCUSSION:**

Agreement State licenses currently comprise approximately 75% of the national total. With the forecast of four more States signing agreements by FY 2003, Agreement State licenses soon may comprise over 80% of the national total. In acknowledgment of this reallocation of licenses, NRC is placing more emphasis on program activities in support of the national infrastructure, particularly with emphasis on program activities such as rulemaking and guidance development activities, information technology systems, technical support, event follow-up, and Integrated Materials Performance Evaluation Program (IMPEP). These activities have a fee impact on an increasingly smaller number of NRC licenses.

Although NRC and Agreement State staff refer to a "National Materials Program," or use similar references (e.g., coherent nationwide effort), no clear definition has been established to define what is meant by a National Materials Program (e.g., its structure, characteristics, makeup, functions and resources). Staff believes the following six issues are key to defining and implementing future State and Federal roles under a National Materials Program and need to be addressed:

1. Development of an overall program mission statement with defined "top level" goals and objectives.
2. Delineation of the respective roles and legal responsibilities of NRC and the Agreement States, including the Organization of Agreement States (OAS) and the Conference of Radiation Control Program Directors, Inc., (CRCPD).
3. Delineation of the scope of activities to be covered by the program and the need for statutory changes at both State and Federal levels.
4. Establishment of formal program coordination mechanisms.
5. Establishment of performance indicators and a program assessment process to both measure program performance and to ensure program evolution.
6. Provision/Budgeting of resources at both State and Federal levels.

**APPENDIX A****National Materials Program SECY-99-250 - cont'd**

To address the future of a National Materials Program, staff will establish a working group in accordance with Management Directive 5.3, "NRC and Agreement State Working Groups," to examine the impacts of the increased number of Agreement States and develop options for Commission consideration. The working group would examine potential frameworks through which the regulation of nuclear materials can be accomplished in the future when the size of Agreement State programs will collectively be significantly larger than that of NRC. The working group would need to address these six issues within the context of other related activities. For example, the group's actions must track with the appropriate materials arena goals, measures, and strategies from the new NRC Strategic Plan, once this new Plan is completed by NRC staff, reviewed by our stakeholders, and approved by the Commission. Regarding item 5, in establishing performance indicators and a program assessment process, the working group will need to be sensitive to the ramifications of its output on the indicators already in place in the IMPEP program. These IMPEP indicators were developed with significant input from NRC and the Agreement States, and have proven to be a highly-successful means by which we assess the technical adequacy, and consistency of our regional materials programs, and those in Agreement States.

The working group will be comprised of NRC, Agreement State, and CRCPD staff as follows:

Office of State Programs (OSP) - one representative (.5 FTE)  
Office of Nuclear Material Safety and Safeguards (NMSS) - one representative (.25 FTE)  
Office of the General Council (OGC) - one representative (.25 FTE)  
Regional Office - one representative (.25 FTE)  
CRCPD - one-two representatives (.25-.5 FTE)  
OAS - one-two representatives (.25-.5 FTE)

**RESOURCES:**

Staff believes agency resources of approximately 1.25 FTE, would be required to characterize and frame these issues for Commission review. This effort can be accommodated within the existing budget.

**COORDINATION:**

The Office of the General Counsel has no legal objections. The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections.

William D. Travers  
Executive Director for Operations

**APPENDIX A****Section 274 of the Atomic Energy Act**

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**ATOMIC ENERGY ACT OF 1954****Sec. 274. Cooperation With States.****a. It is the purpose of this section—**

- (1) to recognize the interests of the States in the peaceful uses of atomic energy, and to clarify the respective responsibilities under this Act of the States and the Commission with respect to the regulation of byproduct, source, and special nuclear materials;**
- (2) to recognize the need, and establish programs for cooperation between the States and the Commission with respect to control of radiation hazards associated with use of such materials;**
- (3) to promote an orderly regulatory pattern between the Commission and State governments with respect to nuclear development and use and regulation of byproduct, source, and special nuclear materials;**
- (4) to establish procedures and criteria for discontinuance of certain of the Commission's regulatory responsibilities with respect to byproduct, source, and special nuclear materials, and the assumption thereof by the States;**
- (5) to provide for coordination of the development of radiation standards for the guidance of Federal agencies and cooperation with the States; and**
- (6) to recognize that, as the States improve their capabilities to regulate effectively such materials, additional legislation may be desirable.**

**b. Except as provided in subsection c., the Commission is authorized to enter into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission under Chapters 6, 7, and 8, and Section 161 of this Act, with respect to any one or more of the following materials within the State—**

- (1) byproduct materials as defined in section 11e.(1);**
- (2) byproduct materials as defined in section 11e.(2);**
- (3) source materials;**
- (4) special nuclear materials in quantities not sufficient to form a critical mass.**

**APPENDIX A****Section 274 of the Atomic Energy Act - cont'd**

During the duration of such an agreement it is recognized that the State shall have authority to regulate the materials covered by the agreement for the protection of the public health and safety from radiation hazards.

c. No agreement entered into pursuant to subsection b. shall provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to regulation of—

- (1) the construction and operation of any production or utilization facility or any uranium enrichment facility;
- (2) the export from or import into the United States of byproduct, source, or special nuclear material, or of any production or utilization facility;
- (3) the disposal into the ocean or sea of byproduct, source, or special nuclear waste materials as defined in regulations or orders of the Commission;
- (4) the disposal of such other byproduct, source, or special nuclear material as the Commission determines by regulation or order should, because of the hazards or potential hazards thereof, not be so disposed of without a license from the Commission. The Commission shall also retain authority under any such agreement to make a determination that all applicable standards and requirements have been met prior to termination of a license for byproduct material, as defined in section 11e.(2).

Notwithstanding any agreement between the Commission and any State pursuant to subsection b., the Commission is authorized by rule, regulation, or order to require that the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material shall not transfer possession or control of such product except pursuant to a license issued by the Commission.

d. The Commission shall enter into an agreement under subsection b. of this section with any State if—

- (1) The Governor of that State certifies that the State has a program for the control of radiation hazards adequate to protect the public health and safety with respect to the materials within the State covered by the proposed agreement, and that the State desires to assume regulatory responsibility for such materials; and
- (2) the Commission finds that the State program is in accordance with the requirements of subsection o. and in all other respects compatible with the Commission's program for regulation of such materials, and that the State program is adequate to protect the public health and safety with respect to the materials covered by the proposed agreement.

e. (1) Before any agreement under subsection b. is signed by the Commission, the terms of the proposed agreement and of proposed exemptions pursuant to subsection f. shall be published once each week for four consecutive weeks in the Federal Register; and such opportunity for comment by interested persons on the proposed agreement and exemptions shall be allowed as the Commission determines by regulation or order to be appropriate.

**APPENDIX A****Section 274 of the Atomic Energy Act - cont'd**

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(2) Each proposed agreement shall include the proposed effective date of such proposed agreement or exemptions. The agreement and exemptions shall be published in the Federal Register within thirty days after signature by the Commission and the Governor.

f. The Commission is authorized and directed, by regulation or order, to grant such exemptions from the licensing requirements contained in chapters 6, 7, and 8, and from its regulations applicable to licensees as the Commission finds necessary or appropriate to carry out any agreement entered into pursuant to subsection b. of this section.

g. The Commission is authorized and directed to cooperate with the States in the formulation of standards for protection against hazards of radiation to assure that State and Commission programs for protection against hazards of radiation will be coordinated and compatible.

h. There is hereby established a Federal Radiation Council, consisting of the Secretary of Health, Education, and Welfare, the Chairman of the Atomic Energy Commission, the Secretary of Defense, the Secretary of Commerce, the Secretary of Labor, or their designees, and such other members as shall be appointed by the President. The Council shall consult qualified scientists and experts in radiation matters, including the President of the National Academy of Sciences, the Chairman of the National Committee on Radiation Protection and Measurement, and qualified experts in the field of biology and medicine and in the field of health physics. The Special Assistant to the President for Science and Technology, or his designee, is authorized to attend meetings, participate in the deliberations of, and to advise the Council. The Chairman of the Council shall be designated by the President, from time to time, from among the members of the Council. The Council shall advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States. The Council shall also perform such other functions as the President may assign to it by Executive order.

i. The Commission in carrying out its licensing and regulatory responsibilities under this Act is authorized to enter into agreements with any State, or group of States, to perform inspections or other functions on a cooperative basis as the Commission deems appropriate. The Commission is also authorized to provide training, with or without charge, to employees of, and such other assistance to, any such State or political subdivision thereof or group of States as the Commission deems appropriate. Any such provision or assistance by the Commission shall take into account the additional expenses that may be incurred by a State as a consequence of the State's entering into an agreement with the Commission pursuant to subsection b.

**APPENDIX A****Section 274 of the Atomic Energy Act - cont'd**

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j. (1) The Commission, upon its own initiative after reasonable notice and opportunity for hearing to the State with which an agreement under subsection b. has become effective, or upon request of the Governor of such State, may terminate or suspend all or part of its agreement with the State and reassert the licensing and regulatory authority vested in it under this Act, if the Commission finds that (1) such termination or suspension is required to protect the public health and safety, or (2) the State has not complied with one or more of the requirements of this section. The Commission shall periodically review such agreements and actions taken by the States under the agreements to insure compliance with the provisions of this section.

(2) The Commission, upon its own motion or upon request of the Governor of any State, may, after notifying the Governor, temporarily suspend all or part of its agreement with the State without notice or hearing if, in the judgment of the Commission:

(A) an emergency situation exists with respect to any material covered by such an agreement creating danger which requires immediate action to protect the health or safety of persons either within or outside of the State, and

(B) the State has failed to take steps necessary to contain or eliminate the cause of the danger within a reasonable time after the situation arose.

A temporary suspension under this paragraph shall remain in effect only for such time as the emergency situation exists and shall authorize the Commission to exercise its authority only to the extent necessary to contain or eliminate the danger.

k. Nothing in this section shall be construed to affect the authority of any State or local agency to regulate activities for purposes other than protection against radiation hazards.

l. With respect to each application for Commission license authorizing an activity as to which the Commission's authority is continued pursuant to subsection c., the Commission shall give prompt notice to the State or States in which the activity will be conducted of the filing of the license application; and shall afford reasonable opportunity for State representatives to offer evidence, interrogate witnesses, and advise the Commission as to the application without requiring such representatives to take a position for or against the granting of the application.

m. No agreement entered into under subsection b., and no exemption granted pursuant to subsection f., shall affect the authority of the Commission under subsection 161b. or i. to issue rules, regulations, or orders to protect the common defense and security, to protect restricted data or to guard against the loss or diversion of special nuclear material. For purposes of subsection 161i., activities covered by exemptions granted pursuant to subsection f. shall be deemed to constitute activities authorized pursuant to this Act; and special nuclear material acquired by any person pursuant to such an exemption shall be deemed to have been acquired pursuant to section 53.



**APPENDIX A****Section 274 of the Atomic Energy Act - cont'd**

**n. As used in this section, the term "State" means any State, Territory, or possession of the United States, the Canal Zone, Puerto Rico, and the District of Columbia. As used in this section, the term "agreement" includes any amendment to any agreement.**

**o. In the licensing and regulation of byproduct material, as defined in section 11e. (2) of this Act, or of any activity which results in the production of byproduct material as so defined under an agreement entered into pursuant to subsection b., a State shall require–**

**(1) compliance with the requirements of subsection b. of section 83 (respecting ownership of byproduct material and land), and**

**(2) compliance with standards which shall be adopted by the State for the protection of the public health, safety, and the environment from hazards associated with such material which are equivalent, to the extent practicable, or more stringent than, standards adopted and enforced by the Commission for the same purpose, including requirements and standards promulgated by the Commission and the Administrator of the Environmental Protection Agency pursuant to sections 83, 84, and 275, and**

**(3) procedures which–**

**(A) in the case of licenses, provide procedures under State law which include–**

**(i) an opportunity, after public notice, for written comments and a public hearing, with a transcript,**

**(ii) an opportunity for cross examination, and**

**(iii) a written determination which is based upon findings included in such determination and upon the evidence presented during the public comment period and which is subject to judicial review;**

**(B) in the case of rulemaking, provide an opportunity for public participation through written comments or a public hearing and provide for judicial review of the rule;**

**(C) require for each license which has a significant impact on the human environment a written analysis (which shall be available to the public before the commencement of any such proceedings) of the impact of such license, including any activities conducted pursuant thereto, on the environment, which analysis shall include–**

**(i) an assessment of the radiological and nonradiological impacts to the public health of the activities to be conducted pursuant to such license;**

**(ii) an assessment of any impact on any waterway and groundwater resulting from such activities;**

**APPENDIX A****Section 274 of the Atomic Energy Act - cont'd**

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(iii) consideration of alternatives, including alternative sites and engineering methods, to the activities to be conducted pursuant to such license; and

(iv) consideration of the long-term impacts, including decommissioning, decontamination, and reclamation impacts, associated with activities to be conducted pursuant to such license, including the management of any byproduct material, as defined by section 11e.(2); and

(D) prohibit any major construction activity with respect to such material prior to complying with the provisions of subparagraph (C).

If any State under such agreement imposes upon any licensee any requirement for the payment of funds to such State for the reclamation or long-term maintenance and monitoring of such material, and if transfer to the United States of such material is required in accordance with section 83b. of this Act, such agreement shall be amended by the Commission to provide that such State shall transfer to the United States upon termination of the license issued to such licensee the total amount collected by such State from such licensee for such purpose. If such payments are required, they must be sufficient to ensure compliance with the standards established by the Commission pursuant to section 161x. of this Act. No State shall be required under paragraph (3) to conduct proceedings concerning any license or regulation which would duplicate proceedings conducted by the Commission.

In adopting requirements pursuant to paragraph (2) of this subsection with respect to sites at which ores are processed primarily for their source material content or which are used for the disposal of byproduct material as defined in section 11e.(2), the State may adopt alternatives (including, where appropriate, site-specific alternatives) to the requirements adopted and enforced by the Commission for the same purpose if, after notice and opportunity for public hearing, the Commission determines that such alternatives will achieve a level of stabilization and containment of the sites concerned, and a level of protection for public health, safety, and the environment from radiological and nonradiological hazards associated with such sites, which is equivalent to, to the extent practicable, or more stringent than the level which would be achieved by standards and requirements adopted and enforced by the Commission for the same purpose and any final standards promulgated by the Administrator of the Environmental Protection Agency in accordance with section 275. Such alternative State requirements may take into account local or regional conditions, including geology, topography, hydrology and meteorology.

## **B. Working Group Interactions and Communications**

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- **Communication Plan**
- **Meeting Schedule**
- **Meetings and Outreach Activities**
- **Questions and Comments from NRC Staff**
- **Responses to Stakeholder Questions NEHRC Meeting**
- **Input from Health Physics Society Focus Groups**
  - South Texas Chapter**
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## APPENDIX B

# Communication Plan

### General Overview

*The NRC and States are in the process of developing options for a National Materials Program which will potentially offer opportunities for NRC, Agreement and non-Agreement States to work together in a more collaborative manner to achieve efficiencies in implementing our individual and joint responsibilities for regulating the use of radioactive materials and radiation sources. A Working Group has been formed, at the direction of the NRC Commission, to develop various options for implementing such a program. The Working Group has identified a need to provide information to various stakeholders on development of options that will be presented to the Commission and to seek feedback from its stakeholders during product development and once a draft product is completed. This communication plan provides an approach for meeting this need.*

### Objectives

1. *Provide information to stakeholders in a timely manner, as the product is developed*
2. *Create positive stakeholder perception by seeking feedback from stakeholders as products are developed and working in a collaborative manner with all stakeholders to develop recommendations for the Commission*
3. *Engage misconceptions, correct inaccurate information, and reduce uncertainty*
4. *Actively engage stakeholders at all levels by soliciting feedback and maintaining positive relationships*
5. *Identify issues involving a cultural transition of NRC, State and other stakeholders and seek feedback on how these issues can be addressed*
6. *Consider stakeholder comments in Working Group products*

### Stakeholders

- *NRC Staff: HQ, Various Program Offices, Regions*
- *Agreement and non-Agreement State Staff*
- *Other Regulatory Agencies: EPA, OSHA, DOT, FDA, DOE, DOL, MSHA, DOI*
- *Licensees*
- *The Public*
- *Industry Representatives: Manufacturers, Consultants, Professional Organizations (SNM, AMA, HPS, ASNT, SMA, NMA, NEI )*
- *Standards Organizations: NIST, ASME, ASNT, ANSI, ICRP, NCRP, IAEA*
- *OMB*
- *Congress and State legislatures*
- *Citizen and Environmental Groups*

## APPENDIX B

### Communication Plan - cont'd

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#### Communication Tools and Opportunities

- *NRC Web Site and Written Communications: OSTP/NMPWG site, NMSS Newsletter, Regional Web Sites or Newsletters, NR&C*
- *State Web Sites and Written Communications: Radrap, CRCPD Newsletter*
- *Federal Register*
- *Industry/Professional Written Communications: HPS Newsletter, ASNT Newsletter, Journal of Nuclear Medicine, etc.*
- *Industry and Professional Meetings: HPS, ASNT, SNM, etc.*
- *State/NRC Interface: CRCPD meeting/poster session, OAS meetings and conference calls, NERHC, NRC Counterpart Meetings*
- *Public Affairs Interface*
- *Pilot Projects: OAS tabletop exercise*
- *Senior Management Interface: EDO, Commissioner Technical Assistants, Senior Management Meeting, IMNS Director's Conference Calls, Commission Briefing*

#### Message Development and Objectives

- *Provide information on draft product, while in progress, to stakeholders and obtain feedback*
- *Distribute messages directly to all levels of stakeholders and encourage individual participation*
- *Consider stakeholder comments in developing Working Group products and provide feedback to stakeholders regarding resolution or outcome*
- *Provide consistent messages by various communicators*
- *Provide a planned/structured communication approach corresponding to the various stages of product development; the communication plan should account for the challenges associated with the scope and complexity of the project at various stages in development*
- *Account for the different perspectives of and needs for communication with external stakeholders*

## APPENDIX B

### Communication Plan - cont'd

#### Key Messages

- *Maintain safety by establishing a regulatory oversight framework that ensures that materials licensees continue to conduct activities involving use of radioactive materials and radiation sources in a safe manner. The States and NRC have done an excellent job in regulating materials users; however, due to the continued shift in regulatory oversight responsibilities and authorities from NRC to Agreement States, a more collaborative approach is needed. This approach should seek to balance use of resources between the States and NRC and distribute the resource burden more equitably between Agreement State and NRC licensees. Maintaining regulatory programs that are adequate to protect public health and safety is a priority in evaluating potential changes.*
- *Enhance public confidence by 1) increasing consistency and predictability in regulatory approach, while recognizing the need for flexibility among State and Federal regulatory programs, and 2) improving efficiency in implementing our regulatory oversight responsibilities.*
- *Improve the effectiveness and efficiency of regulatory programs nationwide by enhancing collaboration, through exchange of information and resources, promoting consensus among regulatory agencies and optimizing use of resources on a national level.*
- *Reduce unnecessary regulatory burden by promoting a consistent regulatory approach nationwide which will offer efficiencies for licensees and greater predictability for stakeholders.*

#### NRC Stakeholders:

- *Keeping NRC employees informed of current Working Group activities*
- *Enhance stakeholder understanding of the draft product being developed and the process used by the Working Group*
- *Minimize concerns regarding potential changes in their roles as a regulator and potential transition in organization or activities*
- *Seek and respond to comments and feedback of stakeholders*

## APPENDIX B

### Communication Plan - cont'd

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#### State Regulatory Stakeholders:

- *Keeping State radiation control program staffs informed of current Working Group activities*
- *Enhance stakeholder understanding of the draft product being developed and the process used by the Working Group*
- *Minimize concerns regarding potential changes in their roles as a regulator and potential transition in organization or activities*
- *Seek and respond to comments and feedback of stakeholders*

#### Other Regulatory Stakeholders (EPA, OSHA, DOT, FDA and others):

- *Informing other potentially affected regulatory stakeholders of current Working Group activities*
- *Enhance stakeholder understanding of the draft product and its potential impact on any shared responsibilities or areas of interest*
- *Seek feedback on potential impacts on other regulated activities or relationships between regulatory agencies (State and Federal)*

#### Industry and Licensee Stakeholders

- *Keep regulated stakeholders informed of Working Group activities*
- *Enhance stakeholder understanding of potential impacts of the draft product on stakeholder licensed activities*
- *Seek input on areas where regulatory burden can be decreased and efficiency enhanced*
- *Seek feedback and respond to stakeholders*

#### Public

- *Inform public stakeholders of the issues and Working Group activities*
- *Seek feedback on whether proposed options meet strategic goals (e.g., maintain public health and safety, increase efficiency and effectiveness, etc.)*
- *Seek feedback and respond to stakeholders*

## APPENDIX B

### Communication Plan - cont'd

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#### Citizen and Environmental Groups

- *Inform public stakeholders of the issues and Working Group activities*
- *Seek feedback on whether proposed options meet strategic goals (e.g., maintain public health and safety, increase efficiency and effectiveness, etc.)*
- *Seek feedback and respond to stakeholders*

#### Working with Regulatory Stakeholders

*The Working Group recognizes that options developed for the National Materials Program and adopted by the Commission may change relationships between the Regions, NMSS, OSTP and the States. Since these changes will affect how administrative and technical staffs for NRC and States perform their work, it is important that the Working Group provide these groups with information on the screening process and options and solicit their comments and input during the process of developing recommendations. Although dissemination of information will primarily be done using electronic and written communications, the Working Group considers it important to meet with stakeholders and make presentations at NRC and Agreement State offices and regional and national meetings to transmit key messages, provide updates on current activities and solicit input from staff, supervisors and management.*

*The Working Group plans to visit each of the NRC regional offices and headquarters during the development phase of the project and when the draft Commission Paper is prepared to make a presentation to NRC regulatory stakeholders to solicit their input. Outreach targeted at State regulatory stakeholders will include a poster presentation at the CRCPD annual meeting, a table top exercise at the annual OAS meeting, and a presentation and poster at the annual NERHC meeting. The Working Group has also scheduled its meetings at NRC and State offices to provide ready access for regulatory stakeholders.*

#### Working with Non-Regulatory Stakeholders (licensees and public)

*The Working Group recognizes that non-regulatory stakeholders' activities may also be impacted by options developed for the National Materials Program and adopted by the Commission. NRC and Agreement State licensees may be affected by changes in regulatory programs at the State and Federal level; therefore, it is important that licensees be made aware of the Working Group's efforts and provided opportunities to give their input during the development of options and recommendations. The Working Group is seeking*



## APPENDIX B

### Communication Plan - cont'd

*opportunities to receive input from licensees, particularly regarding issues relating to improving efficiencies and identifying areas where changes in the materials regulatory program could lead to reduction in regulatory burden while maintaining the current safety goals.*

*Consistent with the common goal of enhancing public confidence in our regulatory programs, the Working Group also recognizes that it is desirable to seek input from public stakeholders regarding any proposed changes to the materials regulatory program. Thus, the Working Group will examine methods by which we can actively engage public stakeholders by both providing information and seeking their input.*

*Although dissemination of information will primarily be done using electronic and written communications, the Working Group will seek opportunities to meet with non-regulatory stakeholders during the development phase of the project. This will include opening Working Group meetings to attendance by the public and presentations during industry and licensee workshops and meetings.*

#### Pilot Projects

*The Working Group plans to conduct a pilot project in conjunction with the annual OAS meeting. The pilot project will consist of an exercise involving representatives of the Agreement States and NRC in which the representatives will attempt to reach a consensus decision on regulatory priorities based on each agency's rulemaking and guidance development agendas. This pilot will provide the Working Group the opportunity to "field test" a key component of a national materials program. It will also provide the regulatory stakeholders the opportunity to compare individual agency agenda with their own and provide the Working Group feedback on the viability of sharing regulatory priorities and reaching a common agenda.*

*CRCPD G-34 Committee proposed a process for establishing a certification committee comprised of OAS, CRCPD and NRC members. The committee would act as certifying entity to review and approve certification regulations submitted by other agencies or groups.*

## APPENDIX B

### Communication Plan - cont'd

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#### Electronic Communications

*The use of electronic communications is a key mechanism for providing stakeholders information and soliciting input and feedback from regulatory and non-regulatory stakeholders. The Working Group has established a web page, located with the OSTP web page, which is accessible to both regulatory and non-regulatory stakeholders. The web page includes the Group's charter, membership, screening criteria, evaluation of program elements, meeting summaries and schedule of meetings, among other products. The web page is maintained with up-to-date information and provides contact information to solicit feedback on the group's products. The Working Group plans to add links to other regulatory and non-regulatory stakeholder web pages.*

#### Stakeholder Communication Issues

*The Working Group has also utilized a joint State and NRC list server (Radrap) as a forum to communicate with regulatory stakeholders and plans to continue to use this resource to solicit input from regulatory stakeholders.*

#### Written Communications

*In addition to the web page, the Working Group plans to prepare articles for CRCPD and HPS newsletters which will include an overview of events and policies leading up to the creation of the Working Group and the development of options and the screening processes used. The articles will also provide information on how stakeholders can provide input to this project.*

#### Meetings

*All working meetings of the Working Group are open to the public and are posted on NRC's web page. A list of planned meetings and presentations are attached.*

#### Interface with Commission Staff

*In order to keep the Commission staff informed, the Working Group will invite the Commissioners' technical assistants to Working Group meetings held in NRC headquarters. The Working Group will brief the technical assistants on the current status of the Working Group's products and solicit their input.*

**Commission Briefing**

*The Commission will be briefed on the recommendations of the Working Group at the conclusion of the project, which is projected for May 2001.*

**APPENDIX B****Meetings and Outreach Activities of the Working Group**

<b>March 6-8, 2000, Rockville, MD (NRC headquarters)</b>	<b>Working Group Meeting</b>
<b>April 10-12, 2000, Arlington, TX (NRC Region IV)</b>	<b>Working Group Meeting</b>
<b>May 15-17, 2000, Tampa, FL</b>	<b>CRCPD Annual Meeting Poster Session</b>
<b>June 5-7, 2000, Denver, CO (State of Colorado Offices)</b>	<b>Working Group Meeting</b>
<b>June 14, 2000, Rockville, MD</b>	<b>Steering Committee Briefing</b>
<b>July 25, 2000, Lisle, IL (NRC Region III)</b>	<b>Presentation to NRC Region III Staff</b>
<b>July 27, 2000, Rockville, MD</b>	<b>Presentation to NRC Standards Developing Organization</b>
<b>August 7, 2000, King of Prussia, PA (NRC Region I)</b>	<b>Presentation to NRC Region I Staff</b>
<b>August 21, 2000, Rockville, MD</b>	<b>Steering Committee Briefing</b>
<b>August 22-24, 2000, Rockville, MD</b>	<b>Working Group Meeting</b>
<b>August 24, 2000, Rockville, MD</b>	<b>Technical Assistants Briefing</b>
<b>September 6, 2000, Atlanta, GA (NRC Region II)</b>	<b>Presentation to NRC Region II Staff</b>
<b>September 11-13, 2000, Lisle, IL</b>	<b>Working Group Meeting</b>
<b>October 2-5, 2000, Charleston, SC</b>	<b>OAS Annual Meeting Presentation to States and Table Top Exercise Working Group Meeting</b>
<b>November 2000, HPS Newsletter</b>	<b>Articles on NMP and NMPWG seen by regulatory and non-regulatory stakeholders</b>
<b>November 2, 2000, Rockville, MD</b>	<b>Presentation to NRC Headquarters Staff</b>
<b>November 11, 2000, Austin, TX</b>	<b>South Texas Chapter Health Physics Society Presentation to Non-Regulatory Stakeholders</b>
<b>November 15, 2000, Mystic, CT</b>	<b>Annual NERHC Meeting Presentation to States and Regional Federal Staff</b>
<b>November 2000, Arlington, TX</b>	<b>Presentation to NRC Staff</b>

**APPENDIX B****Meetings and Outreach Activities of the Working Group - cont'd****December 5-7, 2000, Rockville, MD****Steering Committee Briefing  
Working Group Meeting****December 2000/January 2001, NMSS *Newsletter*****Articles on NMPWG****February 20-23, 2001, Arlington, TX****Working Group Meeting****February 21-22, 2001, Arlington, TX****Public Meeting  
(transcript available at OSTP website)****January 2001, Atlanta, GA****Atlanta Chapter Health Physics Society  
Presentation to Non-Regulatory Stakeholders****March 20-22, 2001, Rockville, MD****Steering Committee Briefing  
Working Group Meeting****March 22, 2001, Princeton, NJ****New Jersey Chapter Health Physics Society  
Presentation to Non-Regulatory Stakeholders****April 3-5, 2001, Atlanta, GA (State of Georgia Offices)****Working Group Meeting****April 29-May 2, 2001, Anchorage, AK****Annual CRCPD Meeting  
Presentation to States**

## APPENDIX B

### Questions and Comments from NRC Staff

The following questions were asked by NRC Staff during outreach presentations on the activities and status of the National Materials Program Working Group (NMPWG) from July through November 2000. Since the NMPWG continued to develop a National Materials Program (NMP) as it interacts with the NRC staff, the questions and comments raised were invaluable to the NMPWG in refining the NMP and clearly communicating the NMP at later meetings with stakeholders. The questions are grouped into four categories: historical, process, structure, and implementation.

#### Historical

- *Has there ever been an example of a major rule making initiated by the States or the CRCPD?*
- *Have other federal entities or agencies pursued the NMP concept with the states?*

#### Process

- *Why are all State National Materials Program Working Group (NMPWG) members from Agreement States?*
- *Who initiated the NMP effort? How will the NMPWG findings be presented to the Commission?*
- *What will the NMPWG use as evaluation criteria for options?*
- *Has the OAS or CRCPD expressed support and need for an NMP?*
- *Who in NRC promoted the SECY paper to initiate the NMPWG?*
- *Does senior NRC management support the NMPWG process?*
- *Is there some way to involve more non-Agreement States in the NMPWG process?*
- *Is there an expectation that the NMPWG propose options to the Commission and give recommendations?*
- *The WG should meet with large non-Agreement states and provide a presentation on what the NMPWG is doing and trying to accomplish (i.e., same outreach the WG is doing with NRC staff).*
- *The NMPWG should return to the Regions when the draft paper is completed.*

#### Structure

- *What is the Conference of Radiation Control Program Directors (CRCPD) and Organization of Agreement States (OAS)?*
- *What are Centers of Excellence/Expertise?*
- *How are State radiation programs funded?*
- *What is meant by an NMP?*
- *The NMPWG needs to consider plural statutes (i.e., those statutes with overlapping interests) when looking at changing the Act.*
- *Will the NMP be an advisory committee or will it bring forth the things that NRC's Office of Nuclear Materials Safety and Safeguards (NMSS) does now?*

## APPENDIX B

### Questions and Comments from NRC Staff - cont'd

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- *Can you give us any insight into what the NMP will look like?*
- *Doesn't the NRC write regulations because they are needed?*
- *The NMPWG should be aware that some states have no infrastructure to participate in an NMP.*
- *Has the NMPWG considered outside sources such as the National Academy of Science (NAS) report on medical regulation by the NRC?*
- *What is compatibility and how is it determined?*

#### Implementation

- *Have all Agreement States bought into the NMPWG process?*
- *If States don't participate in the National Materials Program (NMP), will they still get the benefits?*
- *Why not use a "Work Control Center" to distribute NMP work?*
- *How will the NMP be funded?*
- *If Centers of Excellence/Expertise are used to share resources, how does one address consistency if the compatibility requirements allow States to be more restrictive with some NRC requirements?*
- *Has the NMPWG considered enforcement in the NMP, particularly the need for consistent application of enforcement across jurisdictions and sharing of information?*
- *How would the NMP handle a situation that occurred several years ago when some states explored regulating Veterans Administration (VA) hospitals and the VA shot down the idea in a hurry?*
- *Can the states tell the NRC that a regulation is needed?*
- *How would the NMP handle a recent situation where the NRC went to the States to get consensus on writing a radiography certification exam in Spanish? Although there was compromise reached that was not adequate, consensus did not work on this simple problem. The entire episode was embarrassing and complicated by some states having English only laws.*
- *The NMPWG needs to consider how the NMP will affect the U.S. Territories (Puerto Rico, Guam, etc.).*
- *The NMPWG needs to consider the impact of States entering Indian Tribal lands.*
- *Has the NMPWG considered specific changes needed to the Act?*
- *How long will it take to change the Atomic Energy Act?*
- *If NRC activities are restructured, how will that apply to States and other federal agencies?*
- *The NMP must track and follow centers of excellence/expertise. These centers must be identified rapidly and effectively response to changes in these centers.*
- *How will the NMP identify centers of excellence/expertise? Will the NMPWG come up with the criteria?*
- *Does geography have to be a constraint to identifying centers of excellence/expertise? Can there be multiple centers of excellence/expertise for the same element?*

**APPENDIX B****Responses to Stakeholder Questions at NERHC Meeting****Responses to Questions Distributed to Participants Meeting November 15, 2000**

**What problems have you encountered with interactions with government agencies (State/Federal)?  
How could it be fixed?**

**Lack of uniformity with standards, philosophy, approach to radiation regulatory matters in all Federal agencies. I submit there may be more variation here than between the individual states in many areas.**

**Interagency federal bickering. The fix, have one agency set limits**

**Communication between the NRC and States, i.e., notification of NRC inspection in an Agreement State only after the NRC conducts inspection (no chance for accompaniment) and inconsistent site release standards between federal agencies - States are coming up with their own.**

**Are there any other programs (regulatory or other) that could be used as a model for the National Materials Program (NMP)?**

**Have seen great things develop under the NRC/Agreement State program. The present IMPEP situation is very good. I have noticed recently however that the states seem to have much less respect or consideration from the NRC Commissioners. Maybe one of the NRC Commissioners should be the CRCPD Chairperson or a CRCPD elected official.**

**How could consistency between regulatory programs be improved?**

**Start at the federal levels, more resources**

**You need buy-in of the States. This may be increased with more tie-ins to the CRCPD or OAS. The reason I emphasize the CRCPD is because of the suggested state regulations and the breadth of the working groups.**

**Have only one set of regulations - this set of regulations should be agreed upon by all parties involved.**

**How do you feel about NRC concurring with States on regulatory priorities?**

**Uncomfortable if the NRC is the controlling agency with the States as second class partners. Will we develop a relationship similar to Federal government and Indian Nations? States provide funding with major NRC control?**

**Constitutional issues here.**

**I believe that some States do have better ideas when it comes to regulation and enforcement. I think that IMPEP can adequately identify these areas.**

**This is very important, especially with nuclear power plant decommissioning.**



**APPENDIX B****Responses to Stakeholder Questions at NERHC Meeting  
- cont'd**

**Does NRC need a “lead” function?**

**Too broad an interpretation for an intelligent response**

**Certainly NRC has a national interest and congressional requirements. There should be a lead function but the states need more input. In a democratic society, maybe the states need as much pull in materials issues as we also issue machine licenses and material licenses.**

**Yes**

**Are there additional responsibilities that States should assume?**

**Not known**

**I believe that states already assume all the required responsibilities. We know, however, that some of the CRCPD work done on say, SSRCR Part D, that is not as important as the NRC's Part 20 work being done and thus gets put on the back burner. Maybe we need to integrate the process by elevating the CRCPD process and get better buy-in to the NRC process.**

**What problems do regulatory agencies have working with each other?**

**Turf battles, perverse human nature**

**Lack of definitive direction from above. The agency heads act in a nearly autonomous manner. We understand that the NRC and EPA need to work together on limits for example. The fact that they haven't and that it will only be solved by congressional action eliminates science from the process and is directly the responsibility of the agency heads - a national disservice.**

**How can information sharing among agencies be improved?**

**Continue with the quasi-neutral ground the CRCPD provides.**

**Regular meetings together at a range of different levels.**

**E-mail and web site - RadRap is a great tool now.**

**How would you identify a Center of Expertise?**

**I do not see this as a major issue. Expertise is usually apparent. Perhaps the issue may be to accept the apparent.**

**Rough identification could be based on experience and time. The Texas industrial radiography test is an example. They have the most people with the longest experience.**

**Looking at how much work they have done and how long on a particular issue -, i.e., PET licensing and inspection.**

## APPENDIX B

### Responses to Stakeholder Questions at NERHC Meeting - cont'd

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What are the alternatives to the current system of compatibility designation?

Abolish the concept of “Agreement States” as now seen, as having served its purpose. Control over weapons, source material and such could be returned by the Federal government.

The compatibility designation I think can work very well. The application of the designation and the assignment of the designation are the areas of disagreement. The problem is the subjectivity in the process.

Do you know of any statutes that would impact the Alliance?

I am sure there are many. Start with the point that an individual state is the final authority regarding the health, safety, and welfare of its citizen.

I am unclear on the Alliance and don't feel I can answer this question yet.

Should the Alliance be a regulatory function? Or should the role be extended to “outreach” (i.e., funding a study, etc.)?

At present, with the current climate, developing a regulatory operation will see their results crammed with fish hooks.

If the state were to specifically be included in the process then I expect it would need to be included in the NRC regulations and statutes so as not to be at the whim of the OED and the Commission. But the Alliance shouldn't need to have a regulatory part - Just tie all the available staff together.

If we can't implement the complete Alliance concept as envisioned, what are the minimum changes that you would want?

Abolish the concept of “Agreement States” as now seen, as having served its purpose. Control over weapons, source material as such could be returned by the Federal government.

CRCPD on the NRC Commission.

Regulatory

What role should Non-Agreement States have in the Alliance?

A key question: We see little in this effort that serves non-Agreement States.

I believe that no one should be specifically excluded. I think that they should not hold office or official positions, but they should not be left out. They can still have good ideas.

**APPENDIX B****Responses to Stakeholder Questions at NERHC Meeting  
- cont'd**

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**What role should industry/professional groups have in the Alliance?**

**Same as any other regulatory process. The regulated community, out of necessity, must be fully involved. U.S. philosophy, in part, is consent of the governed to be governed.**

**As the Alliance sees fit. We may need professional help!**

**Their voice should be heard and implement changes they recommend.**

**How can the Working Group best exchange information with State staffs?**

**Through CRCPD.**

**RadRap works well in our State - additional information can be transmitted through CRCPD e-mail.**

**Additional comments and suggestions**

**Just seems on the surface to further the agreement process with incentives to become an Agreement State. Further, assumes radionuclides are the radiation control issue. I submit that machines are an important component, probably larger. Where are they? Radon? This appears to be money driven in part with the advent to non-Agreement States. Perhaps the "Agreement State" concept approaches moribundity.**

## APPENDIX B

### Input from Health Physics Society Focus Groups

South Texas Chapter of the Health Physics Society  
November 11, 2000

What types of issues/problems have you had interacting with government agencies (state or federal)?

A key element that needs to be considered with this effort is a continual reassessment of existing rules, answering the question “do they add any value to the public health?” Ex. Common violation in Texas has to do with package receipt and survey of packages, yet the fact is that packages don’t leak, especially single use packages. Maybe the levels could be change in rule. Consider not adding additional layers of bureaucracy, but look at taking out layers that aren’t adding to public health.

This Alliance should be considering compliance associated with license conditions imposed in lieu of rulemaking. This is considered unconstitutional by circumventing rulemaking process so the violations don’t hold water. Consider a “parking ticket” for that instead of a notice of violation (NOV) process. Licensees are judged by NOV’s received because there are no dead bodies in this industry.

We respond to proposed rules based on workload. Using consensus standards has merit. For instance, the Health Physics Society (HPS) guidance on decommissioning compared to MARSSIM, which is gross and unusable...uranium orders of magnitude more restrictive than MARSSIM. Rely more on industry than on internal government promulgation (rulemaking/guidance).

Compatibility rules come with assumption that rule is going to improve public health and I would argue that point. Is it truly improving public health? Look at any regulatory action to see if really necessary first, regardless of what type of structure implements it.

What has changed with the increased volumes of rules, with exception of radiographers, that has actually done something to improve radiation safety? I would argue that the vast majority of rules have done nothing to directly to improve public health. Go towards performance-based rules, i.e., do you have a program to ensure such and such and are you following it, rather than writing detailed rules. Define the desired outcome rather than the how of getting there and spend time inspecting to ensure licensees are following their safety programs.

Approach should be performance-based using consensus standards...don’t need to reinvent wheels. As long as the outcome is accomplished, fine.

## APPENDIX B

### Input from Health Physics Society Focus Groups - cont'd

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Should a National Materials Program include all types of radiations?

Yes... a licensee finds itself trying to develop policies for their facility and explaining them to several different agencies. It's also hard to explain to users why three different sets of rules apply to radioactive materials. For instance, NESHAPS were written with power plants in mind and those assumptions don't always fit hospitals, academic institutions. It is impossible to manage rules like that.

A VA hospital is an NRC licensee in Texas with x-ray machines and other than byproduct...the NRC jurisdiction very incomplete...if we have problem with something other than byproduct, they throw their hands up and walk away because they don't have jurisdiction. What role has the NRC agreed to play in this (Alliance)? Since AEA limits their role, if they decide not to participate, can they just walk away and do what they do now?

The NRC should get out of the medical side altogether because their oversight's not complete.

I worked at a research reactor and it was NRC inside reactor and TX outside. This creates a lot of unnecessary paperwork which would certainly be eased with one set of regulators.

What do you see as your role in the Alliance (as a professional society and as a licensee)?

How much do professional society's have a role in this? Like HPS, what is their input and what has their involvement been so far?

Does one entity need to have a lead function in the Alliance?

In TX, we went from BRC handling all waste issues to having it split out into several state agencies and then coming back together, but its still not under one roof. How many other states are in the same boat? Do you have everybody at the table to address these kinds of issues across all RAM issues (like Texas Railroad Commission and Texas Natural Resources Conservation Commission) ...rather than forming a fiefdom system where someone can say, wait a minute I'm not playing that game because you didn't ask my opinion, so I'm not letting the rad waste folks into the new world order.

I think there should be one lead agency/group and it should be responsible for setting goals and holding the other agencies/groups accountable. This would help lead to consistent regulation and hopefully interpretation. Should it be NRC? I don't think it would have to be. CRCPD or OAS would be possible...or maybe all three together. I believe this would keep everyone focused. I have some concerns that it will be difficult to get everyone (NRC, Agreement states, EPA, waste agencies, etc.) together and work as a consensus group...too many conflicting agendas and it might be difficult to develop a usable product for licensees.

## APPENDIX B

### Input from Health Physics Society Focus Groups - cont'd

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How is a National Materials Program going to be evaluated/assessed?

The challenge you face in getting this group together is how a bunch of regulators are going to identify what a good program is. Each has its own biases towards being regulators and what a good program is. I think it would be nice to have an objective measure of that. The only indication that regulators have is that our rules are a little thicker...how many violations we issue...but evaluation is all within regulatory community. You have to get an objective measure outside of that....something outside of IMPEP. Maybe dosimetry data?...doses per workers in Texas vs. others. Otherwise, an evaluation would be like a bunch of car dealers assessing what's a good car without knowing what the customer wants.

How are you going to know if this works? How are you going to know if the Alliance is a success or failure? What will it be measured against?

Are there other organizations, etc. that could be evaluated as model for a National Materials Program?

I can't think of another health-related entity that gets outside objective evaluation to be able to quantify it to management and other outside stakeholders, but this is an opportunity to take a professional leadership role and say we're going about things that are prudent. Its pretty tough to compare the radiation gig to tangibles in other programs such as vaccinations, heart disease. I don't think regulatory agencies across the country fully appreciate the pressures practicing professionals are under because we can't produce a body count...all that can be produced are violations, license fees, etc. So upper management tends to view it as a paper tiger. Think about objective measures.

ISO 1400 standards might be considered as a model because they are performance-based, not prescriptive. You read two pages before you get to the first "thou shall" and only on last page was the word "record."

Try looking at FFA. They regulate from the manufacturer to operation, but I'm not sure if they're as performance-based as needed.

Make every state an agreement state and leave NRC with reactors.

What are the positive things/negative things you see with the Alliance?

We tend to respond to proposed rules based on our workload. Using consensus standards is a good idea. For instance, the HPS guidance on decommissioning is much better than MARSSIM which is gross and unusable. You should rely more on industry standards than on internal government workings (government development of rulemaking/guidance).

Approach should be performance-based using consensus standards. You don't need to reinvent wheels. As long as the desired outcome is accomplished, fine.

## APPENDIX B

### Input from Health Physics Society Focus Groups - cont'd

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I would hate to see us lose, as a consequence of “nationalizing,” some of the latitudes that states have that allow us to operate in a more reasonable fashion. For instance, Texas’ 300-day half-life rule is risk-based, safe, and provides cost savings. If a national structure can allow that latitude for positive and pragmatic rules/ guidance, that’s a good thing.

If this group could come up with consistent set of rules that apply to all radiation and can do it as briefly as possible that would give us the flexibility to develop our own programs. It would be a tremendous help and allow use of consensus standards. You could shorten the rules by consolidating regulation of different uses into one set of rules, which would allow one inspector from one agency to inspect all radiation use at a facility. This not only saves time, but also gives us better feeling. However, if consensus means putting everyone’s opinion down, you will end up with documents that are thicker than what we have now. Beware of building consensus by adopting everyone’s *opinions*.

Is public safety any better because we have to jump through all the hoops now required under expanded rules for license applications, operation, etc.? Our program is basically the same thing. The rules are so prescriptive that they have removed the flexibility of the RSO at a facility to come up with a program to achieve an outcome. The only way to get consensus is to have more performance-based rules rather than very detailed rules.

I am often frustrated by differences in knowledge of regulators on certain topics. No one regulator can be knowledgeable on every single topic. If I have ten radiation “topics” in my facility, I’m very knowledgeable about those and I’ve hit regulator that’s not...I get frustrated. By using centers of expertise, our jobs would be easier because we would be communicating on same plane and we wouldn’t have to explain or teach along the way. Using centers of excellence might make the process easier. It would be unreasonable to believe that any one licensee could be expert in all health physics areas, so its also unreasonable to believe that regulators should be expert in all fields.

Would the Alliance have any implications for getting individual states to get their waste disposal acts together?

Waste is a system that’s broken. NRC separated the issue of power plant waste vs. everyone else’s waste so the power plants have more of a solution, but we in the states can’t separate the two. NRC is doing things for power plants...entombment, rubblization...but these give no relief to waste problems other entities face. We need to bring those back together.

In the Alliance, we could have more of opportunity to input (just like we’re doing here). What we would like to see in rulemaking is to get consensus from licensees and more consistency in rules...a uniform set of rules.

What’s working with the system now? Dose limits/standards. The rules should just set out standards and don’t prescribe how to meet those. Be consistent with standards and use compliance with those standards as an objective measure.

**APPENDIX B****Input from Health Physics Society Focus Groups -  
cont'd**

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Who are the stakeholders and what kind of input has the working group received from stakeholders?

Other stakeholders? Possibly IAEA...consider international agencies in terms of the structure and allowing input from those global entities.

Who is the public..who are you going to approach? The Texas Radiation Advisory Board has general public members...you could invite input from folks like that.

There are a lot of people that are industrial hygienists that are assigned the role of RSO. They have an interest, but don't tend to get involved in groups like HPS because they don't particularly associate themselves as health physicists. Consider other safety professionals that may be in the RSO role. Use list of RSO's that you (Texas BRC) have.

Has any of the work or input been put on the web site to solicit information/input?

Put a link to the NMP web site at BRC web site and at the STCHPS web site.



**APPENDIX B****Input from Health Physics Society Focus Groups -  
cont'd**


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Atlanta Chapter of the Health Physics Society  
January 2001

**What types of issues/problems have you had interacting with government agencies (state or federal)?**

The biggest obstacle I can see is where different agencies (federal/state/local) have conflicting regulations. Normally, the most restrictive is applied, but it would be nice to have one set of rules to follow.

One set of rules & regulations for all states to follow, updated and put into action all at the same time. I think NRC should do this.

Occasional problem of getting a definite answer within a week's time. Often a problem getting copies of government publications that are cited by Agencies, but are no longer in print or on the Internet.

Having worked on both sides, I can appreciate the blinders that can develop in one particular position (job). Effort needs to be constantly placed on looking at the other guy's position/purpose. A balance needs to be struck between the 'law' and true safety and effectiveness, not just meeting the letter of the law. I have, in the past, had difficulty getting access to not only the regulations, but supporting guides and policies.

Staff may not be empowered to work with staff of other groups, leaving intergroup communications to top management rather than to intergroup teams who could be more productive.

**Should a National Materials Program include all types of radiations?**

A National Materials Program should include all types of radiation, including natural. All radiation should be treated the same in the regulations, regardless of its origin.

No (maybe microwave & laser) really not sure where other radiations should be.

No. I have a concern of everything being micro-managed, over-regulated out of all proportion to actual risk levels and harm, as the NRC has done with nuclear medicine. The burdens of paperwork (etc.) in cost, time and manpower have always been grossly underestimated by the government.

I tend to be slow to warm up to change and will have to be convinced that the benefit of including all radiations will result in either more efficient programs or safety and less needless 'paperwork'.

Yes. Medical x-ray and radioactive material should be included under same regulatory umbrella for consistent national protection of the population. A child would not know less harm if their radiation dose was delivered by an unnecessary computerized tomography operation or an unnecessary x-ray than an inadequately shielded radioactive source.

**APPENDIX B****Input from Health Physics Society Focus Groups -  
cont'd**

**What do you see as your role in the Alliance (as a professional society and as a licensee)?**

To show government how radioactivity is used in the 'real world'; how it should be realistically managed to achieve the user's purposes without undue risk to the public. The government should be made aware of the results of studies showing radioactivity's effects on the human body (much less than ever estimated). We should keep government updated on results/benefits achieved from our work with radioactivity.

As a consultant, I will need to try to keep the lines of communication open both ways – to the regulators and to the clients.

Providing advice, guidance, and volunteer time to support radiation safety activities

**Does one entity need to have a lead function in the Alliance?**

There should be a lead entity in order to resolve potential disputes. The national body (NRC) is the natural choice to lead such an Alliance.

Yes (NRC)

There are both advantages to having one lead but there are also disadvantages. I think that the radiation field is so diverse that it will be a major adjustment to put all in one basket. The corporate history at most institutions will fight the change to a one-agency program. Just look at how long it is taking to change over to metric from the OLD ENGLISH.

Yes. Without a lead activity, the program will lack focus. The lead activity should receive Congressional funding for this effort. Perhaps Congress should provide incentives for all states to come under the same regulatory net.

**How is a National Materials Program going to be evaluated/assessed?**

By the NRC (we still need a strong central group)

The NMP will have to be evaluated in a manner to allow three things to still work: (1) Separation of State and Federal; (2) Programs and policies that are based on function not just resources and simple plans to reorganize; (3) Clear and reasonable objectives need to be established and delineated before sweeping changes are put into place.

Under revised NRC regulations under which the Agreement States would function. This would likely require a re-enactment of the Atomic Energy Act under another name (Radiation Oversight Act) to pull in NORM and TENORM.

**APPENDIX B****Input from Health Physics Society Focus Groups -  
cont'd**


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**Are there other organizations, etc. that could be evaluated as model for a National Materials Program?**

**No (need only one, NRC)**

**I have limited knowledge of materials programs but, the MQSA/FDA fee for service-contracted-to-states has potential. Major harmonization with Fed law and the ability of states to modify their laws need to be included in the process.**

**As a concept model, CDC has centers for specific tasks, such as National Center for Environmental Health, National Center for Infectious Diseases, etc. Centers for licensee support could be established (perhaps by a bid process) in various states, such as a National Center for Radiography located in Texas or Louisiana where radiography companies are quite active. Others could include the Center for Medical Therapy, Center for X-Rays, Center for Calibration, Center for Licensing, Center for Operational Oversight, etc. Those centers could specialize in supporting one type or group of licensees, and inter-center functional interfaces would be beneficial. - Amend the Atomic Energy Act to give the licensee overseer authorization to control, manage, license, and audit x-rays, accelerator-produced RAM, NORM, TENORM, etc. - Then change the title of Nuclear Regulatory Commission to break the past mold and lead into a new future. An example is the Radiation Safety Agency, with subgroups called the Centers for Radiation Safety. The emphasis is that radiation can and will be used safely and consistently. - Lean toward using general funds rather than licensee fees, or a combination to ease pressure from both sides.**

**What are the positive things/negative things you see with the Alliance?**

**The Alliance's greatest benefit is probably as an information-sharing group. States and NRC should share their analyses and data so that others do not have to reexamine the same problems or issues.**

**Maybe hard to get agreement if too many folks get involved. Some group needs to step in and say: 'this is the way it is going to be' & all licensees, states, etc., follow the same book of rules at the same time.**

**See all the above**

**Positive: More consistent and manageable set of regulations, more uniform protection of all facets of the public (child health, under represented populations, sensitive populations), reduction or elimination of duplicate effort by multiple regulators with different focuses (reduced size of government), lower cost of regulation. -Negative: Overcoming the rice bowl effect may be emotional, change may initially be painful.**

**APPENDIX B****Input from Health Physics Society Focus Groups -  
cont'd**

New Jersey Chapter Health Physics Society  
March 22, 2001

What types of issues/problems have you had interacting with government agencies (state or federal)?

Different sets of regulations and standards

NRC - very professional; New York State - somewhat political, not professional and misinterprets its own regulations

None (2 times)

Poorly worded regulations; difficult to follow, need to get interpretation from regulatory agency

Inconsistent requirements (e.g., decontamination and decommissioning total effective dose equivalent of 25 mrem/yr for NRC, 15 mrem/yr for New Jersey). Redundant regulations or obsolete regulations that are not updated

Both - technical knowledge isn't as well as I would like

None on routine basis. Lack of consistency from inspector to inspector when they come on site.

Can be inflexible, especially with new or unique situations. Several times I've been told the regulation was not written for that situation, but try to comply anyway.

Should a National Materials Program include all types of radiations?

Yes (3 times)

Yes, because New Jersey is implementing draconian dose limits for NORM in soil (e.g. 3 mrem/yr)

Yes, otherwise, there will always be regulatory agencies against the Alliance (e.g., DOE)

Yes. One consistent voice is the best way to go. Multiple agencies and federal and state involvement is too complicated (just look at asbestos regulations)

No. Neutron sources should be regulated by a single agency. Much more dangerous than the three other types

Should include NORM, accelerator and reactor. Not x-ray, microwave, NMR

Yes, it would make it easier for a safety department

All ionizing radiation sources that are not natural

**APPENDIX B****Input from Health Physics Society Focus Groups -  
cont'd**

**How is a National Materials Program going to be evaluated/assessed?**

How realistic and practical the ultimate program is; Will it have money; How it encourages or discourages commerce

Take evaluations from each license holder

Will it improve on the current way of doing business

Performance indicators

Did anything bad happen? Is everything accounted for?

Force States into uniform response to licensees. Between states, NY State Department of

Labor does not issue license or regulations to licensees, Massachusetts requires HP

consultants to register. Use federal money to research and publish new regulations  
consensus

Unfortunately, money will be a primary factor

Performance based - are there problems out there and are they being addressed properly?

**How could consistency between regulatory program be improved.**

It would be nice to have overall consistency

A council that involves each state regulation makers might be able to help in consistency

Keep basics uniform across the country. Hard to be consistent with everything in each state.

Agreement on this would be hard to achieve

Have one set of standards for all as viable and feasible. Avoid multiple inspections by  
different regulatory agencies

If I had a good answer to this question, I'd be rich (or at least a decent politician)

Ensure good science goes into regulations. Force a state to perform a justification of  
regulations on doses that are more stringent than NRC regulations - must include risk based  
assessment.

Use a consensus committee

Base concentration limits on dose - period! One agency could control all exposure to  
radiation doses.

Design a single agency for radiation; state or federal or clear demarcations, i.e., all air  
emissions are EPA, occupational exposure NRC, all medical programs by the states

**Are there other organizations, etc. that could be evaluated as model for a National Materials  
Program?**

State EPA agencies

Perhaps organizations outside the United States

Development of MARSSIM manual

**APPENDIX B****Input from Health Physics Society Focus Groups -  
cont'd**

**What do you see as your role in the Alliance (as a professional society and as licensee)?**

To give feedback as far as how well they are doing and what changes are needed  
 Provide comments/insights to be used in formation of policies and regulations  
 Not as a licensee, but a society should have a voice in rule making through commentary and input  
 The Health Physics Society should be separate equal member in the alliance. Separate from State and NRC and corporations/business. Licensees (as businesses) already have a voice through the political entities that would be in the alliance  
 Open minded to listen to issues from another member's viewpoint  
 As a licensee, one set of regulations, especially when one has facilities in a number of states  
 Victim, vocal participant

**Does one entity need to have a lead function in the Alliance?**

Yes (2 times)  
 Depends on what and extent of lead function means  
 The Alliance should have a Commission representing its constituency  
 Yes, federal NRC to ensure overall consistency and a steady driver  
 Yes, it is all well to have it as a committee decision, but there needs to be one leader  
 Yes, probably at the federal level

**What are the positive things/negative things you see with the Alliance?**

Greater freedom for each State is a positive, difficulty with compatibility is a negative  
 Will be hard to get consensus  
 Positive: standardization of statutes, optimal use of resources; Negative: possible lack of adequate representation for Non-Agreement States  
 Positive: stop redundancy, move NRC from parent to adult role in dealing with licensees.  
 Negative: a consensus decision is hard to come by (no quick decision), will probably cost more on administrative costs, loss of good science to balance view  
 Some states will resist any change  
 I need to hear more about it

## **C. Evaluation of Program Elements**

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- **Summary of Program Element Evaluations**
- **Materials Licensing Guidance**
- **Materials Inspection Guidance**
- **Materials Licensing and Inspection**
- **Performing Materials Inspection**
- **Performing Materials Licensing**
- **Reciprocity**
- **Technical Guidance Documents**
- **Training, Qualification and Experience Standards**
- **Regulatory Program Reviews**
- **Regulatory Program for General Licensees - Regulating Agency**
- **Regulatory Program for General Licensees - Implementation**
- **Certification Program**
- **Rulemaking**
- **Information Infrastructure**

## APPENDIX C

### Summary of Program Element Evaluations

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The Working Group identified and evaluated potential program elements required to support a “National Materials Program” as part of its initial evaluation process. Candidates for the group of program elements were selected by the Working Group based on current program elements common to NRC and Agreement State regulatory programs. The group used IMPEP and CRCPD guidance as a basis for identifying program elements. The following program elements were evaluated:

- Materials licensing, with particular focus on guidance governing the licensing process;
- Materials inspection, with particular focus on guidance governing the inspection process;
- Alternative options for States to perform licensing and inspection functions for all facilities within their respective State;
- Implementation of the materials inspection program;
- Implementation of the materials licensing program;
- Reciprocity, or the States’ and NRC’s process for allowing a materials licensee to conduct licensed operations in areas under another regulatory agency’s jurisdiction;
- Technical Guidance, with specific focus on procedural guidance for specific activities that may be used by licensees in support of their programs or license application submittals;
- Training, Qualification and Experience Standards for regulatory personnel;
- Regulatory program reviews;
- Regulatory program for general licensees;
- Certification Programs;
- Rulemaking;
- Information Infrastructure;
- Incident/Event Response and Coordination;
- Generic Event Assessment; and
- Research (anticipatory and confirmatory)

It should be noted that the program elements were intended to be sufficiently broad to capture a full spectrum of activities. For instance, material licensing is intended to include licensing source, byproduct, and special nuclear material. Thus, these elements include consideration of specific byproduct materials licensees, uranium recovery facilities, and sealed source and device reviews, among other types of licensing activities.



## APPENDIX C

### Summary of Program Element Evaluations - cont'd

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#### Summary of Recommended Alternatives for Program Elements

##### *Materials Licensing Guidance*

NRC/Agreement States (AS) should jointly develop an agenda and priorities for developing licensing guidance. NRC/AS either use working groups to develop guidance or direct other organizations/entities to develop guidance when appropriate.

##### *Materials Inspection Guidance*

NRC/AS should jointly establish priorities and develop inspection guidance. Joint working groups should be used to develop guidance. Alternatively, NRC/AS may also accept consensus standards (following review and revision, if needed) or contract with other organizations to develop guidance when not available and needed.

##### *Materials Licensing and Inspection - Alternative for States to Perform Licensing and Inspection for All Facilities within Their Respective State*

The Working Group requires input from OGC regarding legal issues that may be associated with AS either being granted statutory authority or delegated authority to perform licensing, inspection and enforcement for Federal and other facilities normally regulated by NRC.

##### *Performing Materials Inspections*

Maintain the current inspection program, but supplement the existing program with other options. NRC would perform inspections for all facilities authorized to possess/use AEA materials in non-AS and at federal facilities in AS. NRC would also perform inspections of general licensees and exempt distribution licensees located in non-AS and AS. AS would inspect facilities located in their respective states. Supplemental options would include: 1) allowing other entities to contract with NRC/AS to perform inspections and report results to the appropriate regulatory agency; 2) allowing licensees to perform self-audits which may be accepted in lieu of inspection by NRC/AS or reduce inspection effort by NRC/AS; 3) accept audits performed by other organizations and use these as a supplement to NRC/AS inspections to reduce inspection effort by NRC/AS; and 4) use "Centers of Excellence" to perform inspections of specific technical areas. Acceptance of licensee audits or audits performed by independent organizations to modify NRC/AS inspection effort would be determined by the appropriate regulatory agency in a selective manner. "Centers of Excellence" could be either AS or NRC organizations and would be jointly recognized by AS/NRC.

## APPENDIX C

### Summary of Program Element Evaluations - cont'd

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#### *Performing Materials Licensing*

Maintain the current program and enhance both NRC and AS reviews through use of contracted entities or “Centers of Excellence” to perform some license reviews or portions of reviews for specific technical areas.

#### *Reciprocity*

The Working Group solicited comments from State stakeholders on this issue since NRC is the only regulatory agency that enters another agency’s domain to conduct inspections of licensees working under reciprocity. (Note: AS cannot enter another State to conduct inspections of AS or NRC licensees working within their State.) Based on comments received, the Working Group determined that a recommendation for change in this area was not warranted at this time. The Working Group’s conclusion would not preclude examination of this process under a separate initiative.

#### *Technical Guidance Documents*

Some organization would maintain a clearinghouse of technical documents evaluated and approved by the National Materials Program for use. Consensus on priorities, needs and recommendations for organizations to develop guidance should be jointly established by NRC/AS.

#### *Training, Qualifications & Experience Standards for Regulatory Personnel*

Maintain the current program and enhance with: 1) use of a clearinghouse of training ideas, resources and opportunities designed for or employed by NRC/AS; 2) allowing licensees to provide training, on a voluntary basis, for specific technical issues or consider contracting with licensees to train staff in specific technical areas; and 3) encourage a regulatory agency exchange program to develop staff in specific technical areas.

#### *Regulatory Program Reviews*

Utilize team (NRC/AS) effort in conducting program reviews using IMPEP guidance, but fully implement use of “Centers of Excellence” to assist with team composition.

#### *Regulatory Authority for General Licensees - Regulatory Agency*

This needs to be examined concurrently with the following element. The Working Group recommends that this be discussed with the Steering Committee for consideration of whether a second working group should evaluate the General License program.

## APPENDIX C

### Summary of Program Element Evaluations - cont'd

#### *Regulatory Program for General Licensees - Implementation*

Some of the options were rated by the Working Group; however, given the discrepancies in how these items are regulated and the number of questions regarding the basis for authorizing distribution and use of generally licensed items, the Working Group elected to discuss this element with the Steering Committee. The Working Group is seeking advice on whether this issue should be reviewed by a separate group.

#### *Certification Programs*

Use CRCPD's G-34 Committee Certifying Entity process as an example (with minor modification) of how an element of a National Materials Program could work. Evaluate successes and problems identified by G-34 during initial implementation of the process, and document input received from G-34 with the working group's report.

#### *Rulemaking*

NRC/AS jointly develop a rulemaking agenda and establish a cooperative group to draft rules, using "Centers of Excellence" where possible.

#### *Incident/Event Response*

Maintain certain aspects of the current system, i.e., use of a centralized public event reporting system, consolidated reports to Congress and coordination of contacts between Federal and State agencies, with enhancements. Enhancements would include joint development of guidance and procedures for posting event reports to public information systems and AS assuming greater responsibility for entering event data in public systems. Continued coordination of event response between NRC and AS when necessary would facilitate prompt notification of all affected parties for events which cross jurisdictional boundaries or involve generic safety concerns. AS would also assume greater responsibility for preparing input for the annual Abnormal Occurrence report.

#### *Generic Assessment for Events*

Maintain some elements of the current program with enhancements, including: 1) have AS assume greater responsibility for generic assessment and for drafting proposed actions; 2) have AS assume a more active role in making decisions on appropriate responses to significant generic issues; and 3) seek broader input in decision making for long-term actions. Elements of the existing program that would be retained include NRC internal use of a Generic Assessment Panel (GAP) process and centralized review of proposed actions for both short- and long-term. This contributes to consistency in regulatory approach over a period of time and allows all parties an opportunity to participate in decision making.

**APPENDIX C****Summary of Program Elements Evaluations - cont'd**

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***Materials Research***

AS and NRC identify research priorities and needs and jointly prioritize common research activities on a national level. Specific individual needs could continue to be funded and carried out as is currently done. Joint, collaborative work could be funded through shared resources, and product scope and acceptance would be jointly determined. For those research projects representing emerging needs for several parties, funding and resource expenditures could be pro-rated for regulatory programs, based on the number of licensees that might benefit from the research product.

## APPENDIX C

### Summary of Program Element Evaluations - cont'd

#### Process for Evaluation of Program Elements

The process used by the Working Group included identification of existing processes or methods for accomplishing program goals within State and NRC regulatory programs, as well as other options for each program element. Additional options evaluated by the Working Group included, in some instances, elimination of the program element as well as alternatives for accomplishing the specified outcome. Each option, including the existing mechanisms, was evaluated against criteria defined in the Working Group's Mission Statement. These included:

- A. whether the option optimized resources of Federal, State, professional and industry organizations;
- B. whether the option recognized individual program needs and abilities;
- C. whether the option promoted consensus on regulatory priorities;
- D. whether the option promoted consistent exchange of information between regulatory programs;
- E. whether the option promoted harmonization of regulatory approaches; and
- F. whether the option recognized State and Federal needs for flexibility.

The Working Group created a matrix to evaluate options for each Program Element against the evaluation criteria described above. These evaluation criteria appear as items A through F (corresponding to the criteria listed above) across the top of each matrix.

Each set of options begins by defining the current methods for accomplishing each program element. Row 1 of each matrix represents a baseline from which to evaluate other options. Subsequent rows represent other options identified for each program element. "0" means the option was rated equivalent to the existing method or option; "+" means the option was rated as an improvement for the specific criteria; and "-" means the option was rated as less desirable than the existing method or option.

Based upon the ratings of all options, the Working Group summarized the results into recommendations, which are summarized on pages 6.42 through 6.45.

## APPENDIX C

### Materials Licensing Guidance

#### Options

1. No change from current. NRC develops licensing guidance for byproduct, source and special nuclear material licenses and requests input from AS, and AS also develop guidance for activities that NRC does not regulate and shares guidance with other States (CRCPD coordinates with States on some licensing guidance development).
2. NRC/AS jointly develop an agenda and priorities for developing licensing guidance and establish joint working groups to develop guidance.
3. NRC/AS jointly develop an agenda and priorities for developing licensing guidance and provide direction to an independent entity (CRCPD, ICRP, NCRP, HPS, professional organizations, etc.) that would develop the guidance documents.
4. No coordination between NRC and AS; NRC and individual AS develop guidance based on determined needs, including developing no guidance.
5. NRC/AS accept consensus standards for licensing guidance without further evaluation.

	A	B	C	D	E	F
1	0	0	0	0	0	0
2	+	+	+	+	+	0
3	+	+	+	+	+	0
4	-	0	-	-	-	0
5	+	+	0	+	0	0

**Recommendations:** NRC/AS jointly develop an agenda and priorities for developing licensing guidance. NRC/AS either use working groups to develop guidance or direct other organizations/entities to develop guidance when appropriate. This recommendation is a combination of options 2 and 3.

**Note:** One additional potential option was identified and dismissed by the Working Group. This option was to discontinue licensing certain categories of material (currently authorized under specific licenses) without substitution of another form of regulatory oversight. The Working Group eliminated this as a viable option and did not screen it. This potential option, if implemented, could have an adverse impact on public health and safety and is not risk-informed. Thus, it was found to be inconsistent with the strategic goal of protecting health and safety.

## APPENDIX C

# Materials Inspection Guidance

### Options

1. No change from current. NRC develops inspection guidance for its programs and AS develop guidance for their programs (recognizing that some States choose to adopt guidance in IMC 2800).
2. NRC/AS jointly develop guidance and establish priorities for this work; joint working groups would be assigned the task of developing guidance.
3. NRC/AS jointly establish priorities for inspection guidance development and either accept available consensus standards (after revision or approval) or contract other organizations to develop guidance under NRC/AS direction.

	A	B	C	D	E	F
1	0	0	0	0	0	0
2	+	0	+	+	+	0
3	+	0	+	+	+	0

**Recommendations:** NRC/AS should jointly establish priorities and develop inspection guidance. Joint working groups should be used to develop guidance. Alternatively, NRC/AS may also accept consensus standards (following review and revision, if needed) or contract with other organizations to develop guidance when not available and needed. This recommendation is a combination of options 2 and 3.

## APPENDIX C

# Materials Licensing and Inspection

### *Alternative for States to Perform Licensing and Inspection for All Facilities Within Their Respective State*

#### Options:

1. No change from current. NRC regulates federal facilities and other entities (i.e., exempt distribution licensees) located within AS.
2. AS is granted statutory authority to perform licensing, inspection and enforcement for Federal facilities and other entities normally regulated by NRC (i.e., exempt distribution licensees and others).
3. AS are delegated authority (AS acts as NRC's agent) to perform licensing and inspection for Federal facilities and other entities normally regulated by NRC (i.e., exempt distribution licensees).

	A	B	C	D	E	F
1	0	0	0	0	0	0
2	-	0	0	0	0	0
3	0	0	0	0	0	0

**Note:** Option 2 was found to result in increased resource utilization for regulatory agencies since Master Materials Licensees, large broad-scope licensees and certain multi-site licensees (i.e., USDA and some U.S. Army facilities) would no longer perform permitting and inspection activities for their facilities.

**Recommendation:** No recommendations for change. The Working Group requires input from OGC regarding legal issues that may be associated with AS either being granted statutory authority or delegated authority to perform licensing, inspection and enforcement for Federal and other facilities normally regulated by NRC.



**APPENDIX C****Performing Materials Inspection**  

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**Options:**

1. No change from current. NRC performs inspections for all facilities authorized to possess/use AEA material in non-AS and at federal facilities in AS. NRC also performs inspections of general licensees and exempt distribution licensees located in non-AS and AS. AS inspect facilities located in their respective States under existing programs.
2. NRC performs all inspections of all licensees in non-AS and AS.
3. AS perform inspections of facilities licensed by the AS, as well as at facilities licensed by NRC within their respective States. (This option does not take into account any legislative changes required for AS to perform inspections of federal facilities.)
4. Maintain the current inspection program (Option 1) and allow other entities to contract to perform inspections and report back to the appropriate regulatory agency (i.e., NRC or AS, depending on facility).
5. Maintain the current inspection program (Option 1) and allow licensees to perform self-inspections/audits (in lieu of inspection by regulatory agency) and report results to appropriate regulatory agency. Licensee self-audits conducted in lieu of inspection by regulatory agency would be determined by regulatory agency.
6. Require all States (non-AS and existing AS) to perform inspections of all licensed facilities located within their respective State.
7. AS performs inspections of AS-licensed activities and NRC-licensed activities when conducting routine inspections of commercial/academic entities that hold AS and NRC licenses. (No change in licensing structure, so no legislative changes would be required.)
8. Accept inspections/audits performed by other organizations and use these inspections to supplement AS/NRC inspection programs. AS/NRC would be selective in accepting results of such inspections. This could narrow the scope of AS/NRC inspections. (Examples of these organizations include other regulatory agency inspections or professional/industry organizations.)
9. Maintain current inspection program and supplement with use of “Centers of Expertise” for performing inspections of specific technical areas. Centers of Expertise could be either AS or NRC organizations, and would be jointly recognized by AS/NRC.

## APPENDIX C

## Performing Materials Inspection

	A	B	C	D	E	F
1	0	0	0	0	0	0
2	-	-	-	-	-	-
3	+	-	-	0	-	-
4	+	+	0	0	-	+
5	+	+	0	0	0	+
6	-	-	0	0	0	-
7	+	0	0	+	0	0
8	+	+	0	0	0	+
9	+	+	0	+	0	+

**Recommendations:** Maintain the current inspection program, but supplement the existing program with other options. NRC would perform inspections for all facilities authorized to possess/use AEA materials in non-AS and at federal facilities in AS. NRC would also perform inspections of general licensees and exempt distribution licensees located in non-AS and AS. AS would inspect facilities located in their respective states. Supplemental options would include: 1) allowing other entities to contract with NRC/AS to perform inspections and report results to the appropriate regulatory agency; 2) allowing licensees to perform self-audits which may be accepted in lieu of inspection by NRC/AS or reduce inspection effort by NRC/AS; 3) accept audits performed by other organizations and use these as a supplement to NRC/AS inspections to reduce inspection effort by NRC/AS; and 4) use “Centers of Expertise” to perform inspections of specific technical areas. Acceptance of licensee audits or audits performed by independent organizations to modify NRC/AS inspection effort would be determined by the appropriate regulatory agency in a selective manner. “Centers of Expertise” could be either AS or NRC organizations and would be jointly recognized by AS/NRC. This recommendation is a combination of options 1, 4, 5, 8 and 9.

## APPENDIX C

# Performing Materials Licensing

### Options:

1. No change from current. NRC licensed AEA materials in non-AS, all federal facilities, exempt distribution, and SNM in greater than formula quantities. AS license AEA & NARM in AS and SNM in less than formula quantities.
2. \*Place all program requirements in regulations; require only notification or registration of materials licensees (name, location, materials to be used).
3. Maintain current program and supplement with contracted entities to perform some license reviews or portions of reviews for specific technical areas.
4. \*Licensees submit abbreviated license applications, indicating program commitments, and regulatory agencies review for completeness. This option would not require a detailed submittal of procedures to be used by the licensee.
5. \*Maintain the existing license application process, but regulatory agencies perform administrative reviews for completeness, detailed reviews of licensee procedures would occur during inspections.
6. AS license all facilities within their State (would require change in legislation, but this was not considered for this program element evaluation).
7. NRC licenses all facilities using AEA material.
8. Maintain current program but supplement with “Centers of Expertise” that could be used to perform reviews of specific technical activities.
9. Establish “Centers of Expertise,” consisting of AS/NRC organizations, that conduct all license reviews, based on expertise of each organization.

\*Options 2, 4, and 5 were not evaluated further because they represent methods for performing materials licensing rather than organizations that may be assigned responsibility for materials licensing. The Working Group determined that a change in the level of licensing control should be considered by other working or task groups. This issue is currently being considered by the Phase II Byproduct Material Task Group.

**APPENDIX C****Performing Materials Licensing**

	<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>	<b>F</b>
<b>1</b>	0	0	0	0	0	0
<b>3</b>	+	+	0	0	0	-
<b>6</b>	-	-	0	0	0	-
<b>7</b>	-	-		0	0	-
<b>8</b>	+	+	+	0	+	+
<b>9</b>	0	0	0	0	+	-

**Recommendation:** Maintain the current program and enhance both NRC and AS reviews through use of contracted entities or “Centers of Expertise” to perform some license reviews or portions of reviews for specific technical areas.

## APPENDIX C

### Reciprocity

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#### Options

1. **No change from current: NRC/AS conduct inspections of licensees when working in respective jurisdictions, NRC may choose to conduct inspections at AS licensee's home office (to review activities conducted in areas under NRC jurisdiction), and reciprocity is required and limited to 180 days in any calendar year.**
2. **NRC/AS do not conduct inspections of licensees working under reciprocity in their respective areas of jurisdiction and instead contact the licensing/regulating agency to exchange inspection histories.**
3. **NRC/AS require that the licensee establish an office or record location within the respective area of jurisdiction.**
4. **NRC/AS contract with appropriate regulating agency to conduct inspection of activities conducted under another agency's jurisdiction.**
5. **Abandon reciprocal recognition of NRC/AS licenses by other regulating agencies and require that licensees seek a specific license if they choose to conduct licensable activities in areas under another agency's jurisdiction.**
6. **Do not limit activities conducted under the provisions of reciprocity to 180 days.**
7. **Defer this issue to another working group.**

**The Working Group solicited comments from State stakeholders on this issue since NRC is the only regulatory agency that enters another agency's domain to conduct inspections of licensees working under reciprocity. (Note: AS cannot enter another State to conduct inspections of AS or NRC licensees working within their State.) Based on comments received, the Working Group determined that a recommendation for change in this area was not warranted at this time. The Working Group's conclusion would not preclude examination of this process under a separate initiative.**

## APPENDIX C

### Technical Guidance Documents

**Note:** Technical guidance documents refer to guidance developed for use by licensees and industry in meeting regulatory requirements. Such guidance may be adopted by licensees to support their program requirements or licensing requirements for both NRC and AS.

#### Options

1. No change from current. NRC and States develop such guidance or adopt guidance from Standards Development Organizations (SDOs), ICRP, NCRP, or allow licensees to propose guidance; regulatory agencies would review the documents to ensure that they meet agency/regulatory needs. IAEA or ISO guidance would also be considered.
2. Create a Technical Document clearinghouse for submission, evaluation and development of technical documents. The clearing house would publish the guidance in a catalog or comprehensive volume to make the guidance available to regulatory agencies. IAEA or ISO guidance would also be considered.
3. Allow SDOs to develop guidance and make the guidance available for use by regulatory agencies. (This option would not require acceptance review by NRC/AS.)
4. Contract development of guidance from SDOs based on NRC/AS needs.

	A	B	C	D	E	F
1	0	0	0	0	0	0
2	+	0	0	+	+	0
3	+/-	-	-	-	-	-
4	+	0	+	+	+	0
5	-	+	-	-	-	+

5. NRC/AS develop guidance documents themselves.

**Recommendation:** Some organization would maintain a clearinghouse of technical documents evaluated and approved by the National Materials Program for use. Consensus on priorities, needs and recommendations for organizations to develop guidance should be jointly established by NRC/AS. This recommendation is a combination of options 1 and 2.

## APPENDIX C

# Training, Qualifications & Experience Standards

### Options

1. No change from current. NRC staff is trained and qualified in accordance with MC 1246, and AS develop and train staff in accordance with their program requirements. NRC/OAS continue to develop training programs as an option for States to use. Adequacy of training would be developed during IMPEP reviews.
2. Create central organizations to conduct all training.
3. Maintain Option 1 and create a clearinghouse of training ideas, resources and opportunities designed for or employed by regulatory agencies.
4. Allow licensees to provide training, on a voluntary basis, for specific technical issues/activities. Alternatively, consider contracting with licensees to train regulatory staff in specific technical areas/activities if voluntary initiatives by licensees are not available.
5. Maintain Option 1 and encourage regulatory agency exchange program to develop staff in specific technical areas.
6. Have the NMP coordinate and establish priorities for training, with NRC paying for training to “ensure uniformity.” This was determined to be similar to Option 2 with regard to offering flexibility. In addition, it is based on an underlying assumption that by requiring one regulating agency to pay for all training, uniformity would be ensured because of contracting constraints and decisions made by a single agency.

	A	B	C	D	E	F
1	0	0	0	0	0	0
2	+	-	0	+	+	-
3	+	+	0	+	+	-
4	+	+	0	0	0	+
5	+	+	+	+	+	+
6	-	-	-	-	-	-

**Recommendation:** Maintain the current program and enhance with: 1) use of a clearinghouse of training ideas, resources and opportunities designed for or employed by NRC/AS; 2) allowing licensees to provide training , on a voluntary basis, for specific technical issues or consider contracting with licensees to train

staff in specific technical areas; and 3) encourage a regulatory agency exchange program to develop staff in specific technical areas. This recommendation is a combination of options 3, 4, and 5.



## APPENDIX C

### Regulatory Program Reviews

#### Options

1. No change from current; maintain IMPEP reviews.
2. Eliminate IMPEP reviews and do not replace with alternative; rely upon individual programs to function effectively.
3. NRC/AS implement self-audit programs, evaluating performance against common defined criteria and report to a National Materials Program entity that would be empowered to require corrective action to address deficiencies.
4. NRC/AS implement self-audit programs, evaluating performance against common defined criteria and report to NRC, with NRC empowered to require corrective action to address deficiencies.
5. NRC/AS jointly perform regulatory program reviews more fully utilizing “Centers of Expertise” concept.
6. NRC performs audits of all regulatory programs.
7. NRC/AS contract with an independent entity to perform audits of regulatory programs with results reported to the National Materials Program entity.

	A	B	C	D	E	F
1	0	0	0	0	0	0
2	+	0	-	-	-	+
3	+	-	-	-	-	+
4	+	-	-	-	-	+
5	+	+	0	+	0	0
6	-	-	0	-	-	-
7	0	-	-	-	-	-

**Recommendation:** Utilize team (NRC/AS) effort in conducting program reviews but fully implement use of “Centers of Expertise” to assist with team composition.

## APPENDIX C

# Regulatory Program for General Licensees - Regulatory Agency

**Note:** This element refers only to the entity that would regulate general licensees and the general license program.

### Options:

1. No Change from current. NRC and AS use different mechanisms for providing regulatory oversight for General Licensees, and the level of communication and contact with General Licensees varies widely among the existing regulatory programs.
2. Return the full General License program to the NRC.
3. Regulatory agencies require that manufacturers of generally licensed devices maintain information on entities that have received generally licensed devices. This would include maintaining current information on where the device is located, what entity possesses the device, and information regarding radionuclides and quantities in an entity's possession.
4. An independent entity could be used to track and monitor use of generally licensed devices for all AS and NRC.

**Recommendation:** This needs to be examined concurrently with the following element. The Working

	A	B	C	D	E	F
1	0	0	0	0	0	0
2	+	-	0	-	+	-
3	+	+	0	0	+	+
4	+	+	0	+	+	+

Group recommends that this be discussed with the Steering Committee for consideration of whether a second working group should evaluate the General License program.

**APPENDIX C****Regulatory Program for General Licensees -Implementation**

**Note:** This element refers only to how the general license program is implemented.

**Options:**

1. **No Change from current. NRC and AS use different mechanisms for providing regulatory oversight for General Licensees, and the level of communication and contact with General Licensees varies widely among the existing regulatory programs.**
2. **Modify the regulatory program and make all generally licensed devices exempt from regulation.**
3. **Modify the regulatory program and make all generally licensed devices specifically licensed items.**
4. **Staff each agency (AS and NRC) sufficiently to implement a general licensee program (this does not consider pending implementation of the registration program for NRC).**
5. **Require the manufacturers, who are specifically licensed, to monitor and record the distribution and transfer of generally licensed devices and provide reports to the existing regulatory agencies for review.**
6. **Require that generally licensed devices be leased and not sold. This would result in the manufacturers retaining some responsibility.**
7. **Require that manufacturers identify their customers' locations as an additional location of use on the manufacturers' specific licenses. This would result in the manufacturers retaining some responsibility.**

**Some of the options were rated by the Working Group; however, given the discrepancies in how these items are regulated and the number of questions regarding the basis for authorizing distribution and use of generally licensed items, the Working Group elected to discuss this element with the Steering Committee. The Working Group is seeking advice on whether this issue should be reviewed by a separate group.**

## APPENDIX C

# Certification Programs

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### Options

Use CRCPD's G-34 Committee Certifying Entity process as an example (with minor modification) of how an element of a National Materials Program could work. Evaluate successes and problems identified by G-34 during initial implementation of the process, and document input received from G-34 with the working group's report.

## APPENDIX C

### Rulemaking

#### Options:

1. No change from current. NRC establishes rulemaking agenda, drafts the rule (with AS participation & input for some rules), establishes compatibility category and requires implementation. CRCPD working groups modify NRC rules to adapt for state use. CRCPD drafts rulemaking for non-AEA materials, and States usually adopt these rules. States may also draft rulemaking as needs are identified.
2. NRC/AS jointly develop a rulemaking agenda and establish a cooperative group to draft rules, using “Centers of Expertise” where possible .
3. NRC/AS jointly develop a rulemaking agenda, but NRC drafts rules.
4. NRC/AS jointly develop rulemaking agenda, but NRC and States draft rules independently.
5. NRC/AS jointly develop a rulemaking agenda, but an independent entity (NCRP, HPS, CRCPD) drafts rules for NRC and AS to adopt. (NMPWG determined that this would not optimize resources because of the complications involving contracting the entity.)
6. AS jointly develop a rulemaking agenda, and NRC and AS cooperate in drafting rules.
7. AS jointly develop a rulemaking agenda, and NRC drafts rules.
8. AS jointly develop a rulemaking agenda, and states draft rules independently.
9. AS jointly develop a rulemaking agenda, and an independent entity drafts rules for NRC and AS to adopt. (NMPWG determined that this would not optimize resources because of the complications involving contracting the entity.)

## APPENDIX C

**Rulemaking - cont'd**

	A	B	C	D	E	F
<b>1</b>	0	0	0	0	0	0
<b>2</b>	+	+	+	+	+	0
<b>3</b>	0	0	+	0	0	0
<b>4</b>	-	+	+	-	-	+
<b>5</b>	-	0	+	0	0	0
<b>6</b>	+	0	+	+	+	0
<b>7</b>	0	-	+	0	+	+
<b>8</b>	-	+	+	-	-	+
<b>9</b>	-	0	+	0	0	0

**Recommendation:** NRC/AS jointly develop a rulemaking agenda and establish a cooperative group to draft rules, using “Centers of Expertise” where possible.

## **APPENDIX C**

# **Information Infrastructure**

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**The Working Group identified the following type of information as necessary to support a National Materials Program**

- **Incidents and Events**  
Used for identification of Generic Safety Issues and to track performance
- **Number and Type of Licensees**  
Specific and General licensees
- **Sealed Source and Device Registration Sheets**
- **Escalated Enforcement Actions**
- **Regulations**
- **Licensing and Inspection Guidance**
- **Radiography Certification Process**  
For both individual radiographers and States/Organizations approved for certification
- **Directory Information**  
Identifying regulatory agencies, individuals and addresses
- **Service Providers**  
Waste brokers, recycling organizations/facilities, and sealed source recovery services
- **OSTP procedures**
- **Technical Guidance documents**
- **Program Information (such as provided in OSTP letters)**
- **Training Information (provided by NRC and other organizations)**
- **SNM database**

## APPENDIX C

### Information Infrastructure

The following information systems are currently maintained, but to serve a National Materials Program effectively, they should have linked access through websites.

<b>Information</b>	<b>Maintained by</b>
Rulemaking	NRC, SSRCR, States
Radiography Certification (States/Organizations approved as certifying entities)	OSTP
Sealed Source and Device Registration	NRC
Licensing and Inspection Guidance	NRC, State
Directory Information	HPS, CRCPD, STP
Services	CRCPD, some States
OSTP Procedures	STP, some States
Technical Guidance Documents	NRC
Program Information	STP, NRC, States
Training	NRC, HPS, CRCPD, States



## Appendix C

# Incident/Event Response

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### Options

1. No change from current. NRC maintains centralized information and communication systems to support receipt of event reports from NRC licensees and AS. These systems are also used to facilitate communication between various State and Federal organizations regarding events that occur nationwide. NRC establishes processes with other Federal and State agencies to support interagency communication and response to events of mutual interest. NRC facilitates contact between AS and Federal agencies regarding events of mutual interest when needed, although AS may contact Federal agencies for assistance independent of NRC. NRC coordinates event response with other Federal agencies when needed, for both AS and NRC licensees. AS report events to NRC, and NRC determines criteria for reporting event information in public information systems. NRC compiles data for AS and NRC licensee events that meet Abnormal Occurrence criteria and produces an annual report for Congress.
2. AS independently establish and maintain information and communication systems capable of linking with NRC's system, and States upload data required to support a national event reporting database (with public access equivalent to the current systems). AS become responsible for soliciting support from Federal agencies, independent of NRC, through direct contact with the appropriate Federal agency. Any costs incurred as a result of Federal assistance would be borne by the AS. AS work independently to coordinate event response by multiple States and agencies when incidents or events involve multiple regulatory jurisdictions. AS submit information directly to public information systems in accordance with criteria established by NRC. NRC compiles data for AS and NRC licensee events that meet Abnormal Occurrence criteria and produces an annual report for Congress.
3. NRC and AS receive event notifications and respond independently. Each regulatory agency maintains information and communication systems as deemed necessary to support individual agency functions. No centralized event notification/reporting database exists. Responsibility for coordinating communications and response for events that cross jurisdictional boundaries would rest with the affected agencies. AS submit annual reports of events that meet Abnormal Occurrence criteria to NRC and NRC forwards State reports to Congress collectively with NRC's annual report.
4. NRC and AS jointly establish and maintain an event reporting information system that is accessible to the public. (This would not necessarily replace internal systems used by States or NRC.) NRC and AS review and establish criteria and procedures for posting event reports in public information systems. NRC and AS jointly establish and maintain communications networks to facilitate coordinated communications and response, at State and Federal levels, to events for which an AS may need Federal assistance and those which cross jurisdictional boundaries. NRC and AS collaborate on producing an annual report on those events that meet Abnormal Occurrence criteria.

## Appendix C

### Incident/Event Response - cont'd

	A	B	C	D	E	F
1	0	0	0	0	0	0
2	0	-	-	-	-	0
3	+	+	-	-	-	+
4	+	0	+	+	+	0

**Recommendations:** Maintain certain aspects of the current system, i.e., use of a centralized public event reporting system, consolidated reports to Congress and coordination of contacts between Federal and State agencies, with enhancements. Enhancements would include joint development of guidance and procedures for posting event reports to public information systems and AS assuming greater responsibility for entering event data in public systems. Continued coordination of event response between NRC and AS when necessary would facilitate prompt notification of all affected parties for events which cross jurisdictional boundaries or involve generic safety concerns. AS would also assume greater responsibility for preparing input for the annual Abnormal Occurrence report. This recommendation is a combination of options 1 and 4.

## Appendix C

# Generic Assessment for Events

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### Options

1. **No change from current. NMSS reviews incoming event reports (ENs, PNOs and MRs) and discusses the reports and related information with regional counterparts. Information is developed for each event through interactions with regional and OSTP staffs who, in turn, have gathered additional information from NRC licensees and AS counterparts to support generic risk/safety assessments. NMSS also uses information from the NMED database, Department of Energy weekly reports and other operational data to support weekly reviews by a Generic Assessment Panel (GAP) consisting of NMSS managers and staff. The GAP makes decisions regarding significance of the issue and forwards the issue to a lead division for review, which may result in a short-term follow up action, or recommends that the issue be discussed during a monthly briefing with senior NMSS management. Monthly operational event briefings are supported by NMSS, regional and OSTP staffs, with occasional support from AS staffs. Senior NMSS management determines whether significant issues should be considered for long-term action, such as revision to existing guidance or rulemaking. Events requiring long-term actions are tracked for implementation status by NRC.**
  
2. **The NMSS regional coordinator(s) works with regional counterparts to develop information to support generic risk/safety assessments from existing sources (i.e., licensees, NMED, AS staff, and other operational data sources). Regional staffs work with AS representatives as needed to develop information about events reported by AS licensees. The GAP conducts weekly event reviews, with support from regional and HQ staffs, and determines whether an event should be assigned to a lead division for review (events of lesser significance which may require short-term action) or referred for briefing at the monthly Operational Events briefing. Monthly Operational Event briefings are supported by NMSS and regional staff. Senior NMSS management determines whether significant issues should be considered for long-term action, such as revision to existing guidance or rulemaking. Events requiring long-term actions are tracked for implementation status by NRC.**
  
3. **NRC regional and NMSS staff develop information relating to events reported by NRC licensees and other operational data to support generic risk/safety assessment. NRC regional and NMSS staff and managers conduct generic risk/safety assessment (this may be done using the GAP process) for NRC licensee events. AS develop information relating to events reported by AS licensees and conduct generic risk/safety assessments. NRC and AS determine which of their licensees' events should be reviewed for potential short-term action, based on potential generic implications, and which events are significant enough to be considered for long-term action based on common criteria. Short-term actions are implemented by the NRC and AS, but the substance of the action and information concerning the event is shared between AS and NRC. Information relating to significant events identified as candidates for long-term action is reviewed monthly during a joint Operational Events briefing in which AS and regional staff provide input regarding their respective events and perspectives on appropriate long-term actions. NMSS determines what long-term action should be implemented (with input from AS and regions) when NRC has the lead for implementing the action. NRC would track the status of implementation for these actions. AS could implement actions within their respective programs, as deemed appropriate.**

## Appendix C

### Generic Assessment for Events

4. NRC regional and NMSS staff and managers conduct generic risk/safety assessment (this may be done using the GAP process) of events reported by NRC licensees. AS develop information relating to events reported by AS licensees and conduct generic risk/safety assessments. NRC and AS independently determine which of their licensee's events should be reviewed for potential short-term action, based on potential generic implications, and which events are significant enough to be considered for long-term action. Each agency provides recommendations on proposed actions (i.e., indication that there is no generic implication, draft Information Notice or recommendation for rule change) to NMSS, which serves as a point of contact for monthly Operational Events briefings. Recommendations for action are reviewed jointly (NMSS, regions and AS) during the monthly briefing and a decision is reached on the appropriate course of action.

	A	B	C	D	E	F
1	0	0	0	0	0	0
2	+	0	0	+	0	0
3	+	0	-	+	-	+
4	+	0	+	+	+	0

**Recommendations:** Maintain some elements of the current program with enhancements, including: 1) have AS assume greater responsibility for generic assessment and for drafting proposed actions; 2) have AS assume a more active role in making decisions on appropriate responses to significant generic issues; and 3) seek broader input in decision making for long-term actions. Elements of the existing program that would be retained include NRC internal use of a GAP process and centralized review of proposed actions for both short- and long-term. This contributes to consistency in regulatory approach over a period of time and allows all parties an opportunity to participate in decision making. This is a combination of options 1 and 4.

## Appendix C

# Materials Research

### Options

1. NRC conducts or contracts research projects with costs passed through to NRC licensees. Products of these efforts are generally used to develop generic guidance or, less frequently, to address license-specific issues. Products are public documents and are therefore available for the benefit of AS regulatory programs and licensees, as needed. Research products developed by AS generally benefit State licensees and funding mechanisms are determined in accordance with State requirements.
2. AS continue to identify and fund research activities according to each AS's priority or need. NRC continues to identify and fund research activities according to its priorities or need. AS and NRC make the research products available to all through a centralized information "clearing house" for the benefit of all regulatory programs and licensees.
3. AS and NRC identify research priorities and needs and jointly prioritize common research activities on a national level. Specific individual needs could continue to be funded and carried out as is currently done. Joint, collaborative work could be funded through shared resources, and product scope and acceptance would be jointly determined. For those research projects representing emerging needs for several parties, funding could be pro-rated for regulatory programs, based on the number of licensees that might benefit from the research product.

	A	B	C	D	E	F
1	0	0	0	0	0	0
2	+	0	0	+	0	0
3	+	0	+	+	+	+

**Recommendation:** AS and NRC identify research priorities and needs and jointly prioritize common research activities on a national level. Specific individual needs could continue to be funded and carried out as is currently done. Joint, collaborative work could be funded through shared resources, and product scope and acceptance would be jointly determined. For those research projects representing emerging needs for several parties, funding and resource expenditures could be pro-rated for regulatory programs, based on the number of licensees that might benefit from the research product.

## Appendix D

# Relative Decision Matrix

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The decision matrix is a tool decision-makers can use to assist them in solving problems with multiple, and often competing, evaluation criteria or options. This decision tool is taught at Harvard University and is used among many groups including federal agencies such as the Department of Agriculture and the United States Army. The decision matrix software used by the Working Group was developed for use at the Combined Arms and Services Staff School (CAS<sup>3</sup>) at the U.S. Army Command and General Staff College, Fort Leavenworth, Kansas. The program author was a 1997 graduate of CAS<sup>3</sup>. The program is considered freeware and is intended for dissemination throughout the U.S. Army.

The Working Group used simple non-weighted decision matrices to evaluate the program elements. The Working Group used a “Relative Value” decision matrix to compare all of the final options for a National Materials Program against weighted criteria. The matrix reveals that the logic used by the Working Group was sound when the Working Group recommended the Alliance Option.

The purpose of this appendix is to explain how a decision matrix works and how it can be used in making decisions. A decision matrix compares available options against chosen evaluation criteria that all of the options must meet. Usually in a decision matrix, one criterion is more important in the decision making process than all of the others and a weight factor is assigned to the criterion. For the National Materials Program, protecting public health and safety is the most important evaluation criterion considered. All other criteria being evaluated follow in order of priority and are assigned a weighting factor in the pairwise comparison chart, with the larger values having the most weight. The assignment of weighting factors will make some evaluation criteria more important and some less important. The pairwise comparison chart of the decision matrix process is a structured approach that establishes criteria weights and then applies these weights within the decision matrix. A discussion of the pairwise comparison chart is detailed below.

A basic decision matrix shell is shown in Figure 7.1. Evaluation criteria are shown along the top of the matrix. By convention, evaluation criteria are shown in order of descending weight from left to right in the matrix. Options are shown along the left side of the matrix.

The decision matrix program calculates the totals of each option and shows the values in the far right column of the matrix. Within the decision matrix the lower values are better. The program also re-calculates the option totals whenever a value is changed. The type of matrix selected (Relative Value (RV) or Multiplication) and the Consistency Ratio is shown at the bottom right of the matrix.

## Appendix D

# Relative Decision Matrix

Figure 7.1

Weight	W1	W2	Total
Criteria			
Option			
	RV1	RV2	Total RV
	RV1	RV2	Total RV

Type of Matrix: Relative Value  
 Less Is Better  
 Consistency Ratio =

Either a relative value matrix (RV) or a multiplication matrix can be used for the decision making process. The relative value matrix is the easier of the two methods to use. It is the method of choice when evaluating criteria that do not have a real number values associated with the criteria, i.e. comparing intangibles such as protecting public health and safety, improving public confidence or promoting consensus.

The multiplication matrix is more accurate and used when comparing the magnitude of difference between measurable values. For example, when comparing different types of cars one may be interested in purchasing, a multiplication matrix may contain criteria such as a comparison of actual miles per gallon, cost of the vehicle, cubic feet of cargo space, and mean time between maintenance. This method cannot be used if the Evaluation Criterion cannot be expressed with a numerical value.

The type of matrix used for the Decision Matrix in Section IV is the relative value matrix. This matrix ranks the option based on the value obtained by ranking each option against each of the evaluation criteria. The best option for a particular criterion is assigned a value of one (1). The remaining options are then ranked, ordering them within that evaluation criterion. If two or more options have the same value within a given evaluation criterion, their rankings are averaged and the average is assigned to each of the options. For Example: Two options are tied for the 2nd and 3rd ranking.  $((2+3) / 2 = 2.5)$  Therefore 2.5 would be assigned to the two options and the next option would be assigned a value of four (4), etc.

## Appendix D

# Relative Decision Matrix

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Each relative value is put in the appropriate box corresponding to that combination of option and evaluation criterion. The relative value method computes the total for each option by adding the products of each relative value of the evaluation criteria multiplied times the evaluation criterion's weight for each evaluation criterion along an option row as follows:

$$(RV1)(W1) + (RV2)(W2) + \dots + (RVn)(Wn) = \text{Total REL VAL}$$

Where:  $RVn$  = Relative Value for the assigned value of the  $n$ th Evaluation Criterion

$Wn$  = Weight of the  $n$ th Evaluation Criterion

The pairwise comparison is the technique used to translate a comparison of the relative importance of the evaluation criteria into numerical values and then a mathematical model determines an appropriate weight to accurately reflect the logic. The pairwise comparison lends objectivity to what otherwise would be a simultaneous subjective ranking of many criteria -- something the human mind has difficulty doing. The completed pairwise comparison chart that was used for the relative value matrix in Section IV is shown in Figure 7.2 of this appendix.

To determine criteria weights using the pairwise comparison techniques the evaluation criteria are ranked in order of general importance. Factors and their values for criteria comparison are: (1) Equal, (2) Slightly Favored, (3) Favored, and (4) Strongly Favored. These are used to input the numerical *importance factor* into the chart by comparing each of the evaluation criteria against each of the other criteria. The following example shows the process by which one can determine the pairwise comparison:



## Appendix D

# Relative Decision Matrix

EXAMPLE:

Which evaluation criterion (EC) is more important ... EC #1 or EC#2?

Answer: EC#1

By what *importance factor*?

Answer: 4 (Strongly Favored)

The *importance factor* 4 is entered in the box at the EC #1-EC#2 intersection.

	EC #2	EC #3	EC #4
EC #1	4	4	4
EC #2		2	3
EC #3			1

The evaluation of all pairs is continued until the chart is complete.

Next a logic check is conducted. In general, *importance factors* increase in value or are equal in value as you move from left to right along a row of the chart. If the *importance factors* do not consistently increase or remain the same as you move from left to right in the chart one of two conditions could exist:

(a) Evaluation criteria ranking are out of order: To solve this problem, reorder the order the evaluation criteria and repeat the pairwise comparison; or

(b) The logic of the pairwise comparison is incorrect. To solve this problem, the *importance factors* must be reevaluated.

An additional logic check is conducted within a given evaluation criterion. The values should decrease or remain the same as you move from top to bottom in the chart. Once all of the values are entered in the pairwise comparison chart, the computer calculates the weights for each of the evaluation criteria and imports those values to the decision matrix. The mathematical model that determines the criteria weighting is based on the Eigenvector method described in the monograph "Lecture Notes in Economics and Mathematical Systems." The methodology for solving the Eigenvalues for a specific Eigenvector is described in the book, Matrices and Transformations.

## Appendix D

# Relative Decision Matrix

**Figure 7.2**

Pairwise Comparison Chart

	Optimize Resources	Promote Consensus	Account for Individual Needs	Flexibility	Exchange of Information	Harmonize Regulatory Approaches	Public Confidence
Maintains Safety	4	4	4	4	4	4	4
	Optimize Resources	2	2	2	2	3	2
		Promote Consensus	1	1	1	1	1
			Account for Individual Needs	1	1	1	1
				Flexibility	1	1	1
					Exchange of Information	1	1
						Harmonize Regulatory Approaches	1

### Legend of Importance Factors

- 1 - Equal
- 2 - Slightly Favored
- 3 - Favored
- 4 - Strongly Favored

After the criteria weights have been determined, the program determines the consistency ratio. The consistency ratio uses a least squares method to measures how well the pairwise comparison values maintain a logical series of relationships.

The consistency ratio is shown as a percentage below the right side of the decision matrix. For this mathematical model, a consistency ratio of 95% or more means the logic of the pairwise comparison is acceptable using the weighting factors produced by the decision matrix program. If a consistency ratio below 95% results, an error box appears in the program. If a value below 95% occurs, the pairwise comparison must be re-evaluated for logic errors. The mathematical model that determines the consistency ratio is based on the method described in the book, Spreadsheet Modeling and Decision Analysis: A Practical Introduction to Management Science.

## Appendix D

# Relative Decision Matrix

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With a large number of evaluation criteria, the program model may not catch a single, obvious error in the pairwise comparison logic. This limitation of the model makes conducting the logic check very important, i.e. the user must ensure the pairwise comparison *importance factors* generally increase or are equal in value, as you move from left to right along a row of the chart.

Together with the consistency ratio, sensitivity analysis is a measure of the subjectivity of the decision matrix. Sensitivity analysis identifies the degree to which the decision matrix results are subject to change with only small changes in the evaluation criteria weights. A solution that is not sensitive to changes in weights provides the decision-makers with confidence that they have a valid solution. A solution that is "sensitive" to changes in weights is a red flag for the decision-maker. With a sensitive solution, the decision-maker must review the Pairwise relationships of the criteria to see if they really reflect the decision-maker's understanding of the relative importance of each criteria.

The program conducts sensitivity analysis by changing each Evaluation Criterion weight of 1.0 or more independently, within a range of plus or minus three points, and recalculates the matrix to determine whether the solution changes. The program resets the criterion weight to its original value and proceeds to analyze the sensitivity of the next Evaluation Criterion.

For example: For an Evaluation Criterion weight of 2.38, the program:

Sets the weight incrementally lower by hundredths of a point (e.g., 2.37, 2.36, etc.), it recalculates, and determines the weight where the solution may change. NOTE: In this example, the program does not set the value lower than 1.00 and therefore does not complete the calculation within the full range of -3.

Next the program sets the weight incrementally higher by hundredths of a point (e.g., 2.39, 2.40, etc.), recalculates, and determines the weight where the solution may change. The program stops calculating at the weight of 5.38 to complete the range of +3.

After this calculation is completed the program resets the weight to the original value of 2.38 and moves to analyze the next Evaluation Criterion.

The Sensitivity Analysis for the decision matrix used in Section IV, Recommendations, is shown in Figure 7.3.

## Appendix D

# Relative Decision Matrix

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Figure 7.3

### SENSITIVITY ANALYSIS

Maintains Safety	Not Sensitive
Optimizes Resources	Not Sensitive
Promote Consensus	Not Sensitive
Regulatory Approaches	Not Sensitive
Exchange of Information	Not Sensitive
Public Confidence	Not Sensitive
Account for Individual Needs	Not Sensitive
Flexibility	Not Sensitive

The decision matrix program calculates the totals of each option and shows the values in the far right column of the matrix. The program will re-calculate new totals whenever a value is changed.

The decision matrix is an important tool for making decisions more objective, especially when there are numerous evaluation criteria to be compared to a number of possible options. By using a decision matrix, or similar method, a high degree of confidence is built into the decision making process.

## Section VIII

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